As confidentially submitted to the Securities and Exchange Commission on June 18, 2018 as Amendment No. 2 to the confidential submission dated May 3, 2018

This draft registration statement has not been publically filed with the Securities and Exchange Commission and all information herein remains confidential.

Registration No. 333-

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM S-1

REGISTRATION STATEMENT Under

The Securities Act of 1933

Replimune Group, Inc.

(Exact name of Registrant as specified in its charter)

Delaware

(State or Other Jurisdiction of Incorporation or Organization)

2836 (Primary Standard Industrial Classification Code Number) 82-2082553

(I.R.S. Employer Identification Number)

Replimune Group, Inc. 18 Commerce Way, Woburn, MA 01801 (781) 995-2443

(Address, including zip code, and telephone number, including area code, of Registrant's principal executive offices)

Philip Astley-Sparke, Executive Chairman Replimune Group, Inc. 18 Commerce Way, Woburn, MA 01801 (781) 995-2443

(Name, address, including zip code, and telephone number, including area code, of agent for service)

Please send copies of all communications to:

Timothy J. Corbett Gitte J. Blanchet Morgan, Lewis & Bockius LLP One Federal Street Boston, MA 02110 (617) 341-7700

William V. Fogg Johnny G. Skumpija Cravath, Swaine & Moore LLP Worldwide Plaza 825 Eighth Avenue New York, NY 10019 (212) 474-1000

Approximate date of commencement of the proposed sale to the public: As soon as practicable after the effective date of this Registration Statement.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act, check the following box.

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company or emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer o	Accelerated filer o	Non-accelerated filer 🗵	Smaller reporting company o
		(Do not check if a	Emerging growth company 🗵
		smaller reporting company)	

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided to Section 7(a)(2)(B) of the Securities Act.

CALCULATION OF REGISTRATION FEE

Title of each class of securities to be registered	Proposed maximum aggregate offering price ⁽¹⁾	Amount of registration fee ⁽²⁾
Common stock, par value \$0.001 per share	\$	\$

(1) Includes additional shares of common stock that the underwriters have the option to purchase.

(2) Estimated solely for the purpose of calculating the registration fee pursuant to Rule 457(o) under the Securities Act of 1933, as amended.

The Registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933, as amended, or until the Registration Statement shall become effective on such date as the Securities and Exchange Commission, acting pursuant to said Section 8(a), may determine.

Explanatory note

This Amendment No. 2 to the draft registration statement on Form S-1 is being confidentially submitted solely for the purpose of confidentially submitting Exhibits 10.9 and 10.10. No change is made to the prospectus constituting Part I of this draft registration statement or Items 13, 14, 15, 16(b) or 17 of Part II of this draft registration statement.

Part II Information not required in prospectus

Item 13. Other expenses of issuance and distribution.

The following table sets forth the fees and expenses in connection with the sale of common stock being registered (excluding the underwriting discount). Except for the Securities and Exchange Commission, or SEC, registration fee and the Financial Industry Regulatory Authority, Inc., or FINRA, filing fee, all amounts are estimates.

	Amount paid or to be paid
SEC registration fee	\$
FINRA filing fee	
Nasdag listing fee	
Legal fees and expenses	
Accounting fees and expenses	
Printing expenses	
Transfer agent and registrar fees and expenses	
Miscellaneous	
Total	\$

Item 14. Indemnification of directors and officers.

Section 145 of the Delaware General Corporation Law, or DGCL, authorizes a corporation's board of directors to grant, and authorizes a court to award, indemnity to officers, directors and other corporate agents.

As permitted by Delaware law, our amended and restated certificate of incorporation to be in effect immediately prior to the completion of this offering provides that, to the fullest extent permitted by Delaware law, no director will be personally liable to us or our investors for monetary damages for breach of fiduciary duty as a director. Pursuant to Delaware law, such protection would be not available for liability:

- for any breach of a duty of loyalty to us or our investors;
- for acts or omissions not in good faith or that involve intentional misconduct or a knowing violation of law;
- for any transaction from which the director derived an improper benefit; or
- for an act or omission for which the liability of a director is expressly provided by an applicable statute, including unlawful payments of dividends or unlawful stock repurchases or redemptions as provided in Section 174 of the DGCL.

Our amended and restated certificate of incorporation to be in effect immediately prior to the completion of this offering also provides that if Delaware law is amended after the approval by our investors of the amended and restated certificate of incorporation to authorize corporate action further eliminating or limiting the personal liability of directors, then the liability of our directors will be eliminated or limited to the fullest extent permitted by Delaware law.

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Our amended and restated bylaws to be in effect immediately prior to the completion of this offering further provide that we must indemnify our directors and officers to the fullest extent permitted by Delaware law. Our amended and restated bylaws also authorize us to indemnify any of our employees or agents and permit us to secure insurance on behalf of any officer, director, employee or agent for any liability arising out of his or her action in that capacity, whether or not Delaware law would otherwise permit indemnification.

In addition, our amended and restated bylaws to be in effect immediately prior to the completion of this offering provide that we are required to advance expenses to our directors and officers as incurred in connection with legal proceedings against them for which they may be indemnified and that the rights conferred in the amended and restated bylaws are not exclusive.

We have entered into indemnification agreements with each of our directors and executive officers. These agreements, among other things, would require us to indemnify each director and officer to the fullest extent permitted by Delaware law, the amended and restated certificate of incorporation and amended and restated bylaws, for expenses such as, among other things, attorneys' fees, judgments, fines and settlement amounts incurred by the director or executive officer in any action or proceeding, including any action by or in our right, arising out of the person's services as our director or executive officer or as the director or executive officer of any subsidiary of ours or any other company or enterprise to which the person provides services at our request. Upon the completion of the offering, we intend to obtain and maintain directors' and officers' liability insurance.

The SEC has taken the position that personal liability of directors for violation of the federal securities laws cannot be limited and that indemnification by us for any such violation is unenforceable. The limitation of liability and indemnification provisions in our amended and restated certificate of incorporation and amended and restated bylaws, in each case, to be in effect immediately prior to the completion of this offering, may discourage stockholders from bringing a lawsuit against our directors and officers for breach of their fiduciary duty. They may also reduce the likelihood of derivative litigation against our directors and officers, even though an action, if successful, might benefit us and other stockholders. Further, a stockholder's investment may be adversely affected to the extent that we pay the costs of settlement and damage awards against directors and officers as required by these indemnification provisions.

Item 15. Recent sales of unregistered securities

Set forth below is information regarding securities issued by Replimune Group, Inc. within the past three years that were not registered under the Securities Act of 1933, as amended, or the Securities Act:

In July 2017, in connection with the reorganization, we issued the following shares:

- an aggregate of 200,000 shares of our series seed preferred stock to our series seed investors;
- warrants convertible into an aggregate of 50,000 shares of our series seed preferred stock to our series seed investors;
- an aggregate of 864,533 shares of our series A preferred stock to our series A investors; and
- stock options to purchase an aggregate of 93,501 shares of common stock to our executive officers and employees.

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In July 2017 and September 2017, we sold an aggregate of 861,415 shares of our series B preferred stock to our series B investors at a purchase price per share of \$63.79 resulting in aggregate gross proceeds of approximately \$55 million.

From July 2017 to June 11, 2018, we granted stock options under the 2017 Equity Compensation Plan, or our 2017 Plan, to purchase an aggregate of 160,657 shares of common stock at exercise prices ranging from \$32.82 per share to \$38.09 per share.

The offers and sales of the securities described in the foregoing paragraphs were exempt from registration under either (i) Rule 701 promulgated under the Securities Act in that the transactions were under compensatory benefit plans and contracts relating to compensation as provided under Rule 701 or (ii) in reliance on Regulation D, Rule 506 and/or Section 4(a)(2) under the Securities Act. With respect to the offers and sales that were exempt from registration under Rule 701, the recipients of such securities were our employees, directors or consultants and received the securities under our 2017 Plan. Appropriate legends were affixed to the securities issued in these transactions.

Item 16. Exhibits and financial statement schedules

(a) Exhibits

The exhibits to the registration statement are listed in the Exhibit Index attached hereto and incorporated by reference herein.

(b) Financial statement schedules

All financial statement schedules have been omitted because they are not required or because the required information is given in the consolidated financial statements or notes to those statements.

Item 17. Undertakings.

The undersigned Registrant hereby undertakes to provide to the underwriters at the closing specified in the underwriting agreement, certificates in such denominations and registered in such names as required by the underwriters to permit prompt delivery to each purchaser.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons of the Registrant pursuant to the foregoing provisions, or otherwise, the Registrant has been advised that in the opinion of the SEC such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the Registrant of expenses incurred or paid by a director, officer or controlling person of the Registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the Registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

The Registrant hereby undertakes that:

(1) For purposes of determining any liability under the Securities Act, the information omitted from a form of prospectus filed as part of this registration statement in reliance upon Rule 430A and contained in the form of prospectus filed by the Registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the



Securities Act shall be deemed to be part of this registration statement as of the time it was declared effective.

(2) For the purpose of determining any liability under the Securities Act, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

Number	Description
1.1*	Form of Underwriting Agreement
3.1 [#]	Amended and Restated Certificate of Incorporation of the Registrant, as currently in effect
3.2#	Amended and Restated Bylaws of the Registrant, as currently in effect
3.3*	Form of Certificate of Amendment to Amended and Restated Certificate of Incorporation of the Registrant, effecting a stock split, to be in effect prior to the effectiveness of this registration statement
3.4*	Form of Amended and Restated Certificate of Incorporation of the Registrant, to become effective immediately prior to the completion of this offering
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- 3.5^{*} Form of Amended and Restated Bylaws of the Registrant, to become effective immediately prior to the completion of this offering
- 4.1* Form of Common Stock Certificate of the Registrant
- 4.2[#] Amended and Restated Investors' Rights Agreement, dated July 10, 2017, by and among the Registrant and the investors set forth therein
- 5.1* Opinion of Morgan Lewis and Bockius, LLP
- 10.1* Form of Indemnification Agreement by and between the Registrant and its directors and officers
- 10.2*[†] 2017 Equity Compensation Plan and form of option agreements and notice of exercise
- 10.3*[†] 2018 Omnibus Incentive Compensation Plan and forms of agreements thereunder, to become effective immediately prior to the completion of this offering
- 10.4^{†#}Employment Agreement, effective as of October 1, 2015, by and between Robert Coffin and Replimune, Inc.
- 10.5^{†#}Employment Agreement, effective as of October 1, 2015, by and between Philip Astley-Sparke and Replimune, Inc.
- 10.6^{†#}Employment Agreement, effective as of November 1, 2015, by and between Pamela Esposito and Replimune, Inc.
- 10.7[#] Lease, dated as of April 1, 2016, by and between Cummings Properties, LLC and the Registrant
- 10.8[#] Lease, dated as of April 4, 2016, by and between MEPC Milton Park No. 1 Limited and MEPC Milton Park No. 2 Limited, and the Registrant
- 10.9[‡] Clinical Trial Collaboration and Supply Agreement, dated as of February 26, 2018, by and between Bristol-Myers Squibb Company and the Registrant
- 10.10[‡] Master Clinical Trial Collaboration and Supply Agreement, dated as of May 29, 2018, by and between Regeneron Pharmaceuticals, Inc. and the Registrant
- 23.1* Consent of PricewaterhouseCoopers, Independent Registered Public Accounting Firm
- 23.2* Consent of Morgan, Lewis & Bockius LLP. Reference is made to exhibit 5.1
- 24.1 Power of Attorney. Reference is made to the signature page hereto

Indicates confidential treatment has been requested with respect to specific portions of this exhibit. Omitted portions have been filed with the Securities and Exchange Commission pursuant to Rule 406 of the Securities Act of 1933, as amended.

[#] Previously filed

^{*} To be filed by amendment

[†] Indicates management contract or compensation plan

Signatures

Pursuant to the requirements of the Securities Act of 1933, as amended, the Registrant has duly caused this Registration Statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the city of Woburn, Commonwealth of Massachusetts, on 2018.

REPLIMUNE GROUP, INC.

By:

Robert Coffin, Ph.D. President, Chief Executive Officer and Director

Power of attorney

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Philip Astley-Sparke, Robert Coffin and Stephen Gorgol his true and lawful attorney-in-fact and agent with full power of substitution, for him and in his name, place and stead, in any and all capacities, to sign any and all amendments (including post-effective amendments) to this registration statement, and to sign any registration statement for the same offering covered by the registration statement that is to be effective upon filing pursuant to Rule 462(b) promulgated under the Securities Act of 1933, as amended, and all post-effective amendments thereto, and to file the same, with all exhibits thereto and all documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorney-in-fact and agent, full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the premises, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming that all said attorneys-in-fact and agents or any of them, or his or their substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Act of 1933, as amended, this Registration Statement has been signed by the following persons in the capacities and on the dates indicated.

Name	Title	Date
Robert Coffin, Ph.D.	President, Chief Executive Officer and Director (Principal Executive Officer)	, 2018
Philip Astley-Sparke	Executive Chairman, Treasurer, Secretary and Director	, 2018
Stephen Gorgol	Chief Accounting Officer (Principal Financial and Accounting Officer)	, 2018
Kapil Dhingra	Director	, 2018
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Name		<u>Title</u>	Date
Hyam Levitsky	Director		, 2018
Jason Rhodes	Director		, 2018
Joseph Slattery	Director		, 2018
Otello Stampacchia	Director		, 2018
Sander Slootweg	Director		, 2018
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QuickLinks

Explanatory note

Part II Information not required in prospectus Item 13. Other expenses of issuance and distribution. Item 14. Indemnification of directors and officers. Item 15. Recent sales of unregistered securities Item 16. Exhibits and financial statement schedules Item 17. Undertakings.

Exhibit index

<u>Signatures</u> Power of attorney

REPLIMUNE GROUP, INC. REQUESTS THAT THE MARKED PORTIONS OF THIS EXHIBIT BE GRANTED CONFIDENTIAL TREATMENT UNDER RULE 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED

Execution

CLINICAL TRIAL COLLABORATION AND SUPPLY AGREEMENT

This **CLINICAL TRIAL COLLABORATION AND SUPPLY AGREEMENT** (the "*Agreement*") is made and entered into effective as of the date signed by the last Party to sign below (the "*Effective Date*") by and between **Replimune Inc.**, a corporation organized under the laws of Delaware, having a place of business at 18 Commerce Way, Woburn, MA 01801 (the "*Recipient*") and **Bristol-Myers Squibb Company**, having a place of business at 345 Park Avenue, New York, NY 10154 ("*BMS*"). The Recipient and BMS are sometimes individually referred to in this Agreement as a "*Party*" and collectively as the "*Parties*."

PRELIMINARY STATEMENTS

- A. The Recipient desires to conduct, and BMS desires to supply the BMS Study Drug (as defined below) for the conduct of, a Combined Therapy Clinical Trial (as defined below) in accordance with the Protocol (as defined below) therefor and in accordance with the terms of this Agreement.
- B. The Parties desire to agree on various terms and conditions to govern the Parties' obligations in connection with the performance of the Combined Therapy Clinical Trial.

NOW, THEREFORE, in consideration of the foregoing premises and the mutual promises and covenants contained herein, the Parties agree as follows:

ARTICLE 1

DEFINITIONS

The terms in this Agreement with initial letters capitalized, whether used in the singular or the plural, shall have the meaning set forth below or, if not listed below, the meaning designated in places throughout this Agreement.

"Adverse Event," ("AE") "Serious Adverse Event" ("SAE") and "Serious Adverse Drug Reaction" ("SADR") shall have the meanings provided to such terms in the International Conference on Harmonization ("ICH") guideline for industry on Clinical Safety Data Management (E2A, Definitions and Standards for Expedited Reporting).

"*Affiliates*" means, with respect to a particular Party, an entity that, directly or indirectly, through one or more intermediaries, controls, is controlled by or is under common control with such Party, only for so long as such control exists. As used in this definition, the term "controls" (with correlative meanings for the terms "controlled by" or "under common control with") means (a) that an entity or company owns, directly or indirectly, more than fifty percent (50%) of the voting stock of another entity, or (b) that an entity, person or group otherwise has the actual ability to control and direct the management of the entity, whether by contract or otherwise.

"*Agreement*" shall have the meaning set forth in the preamble to this Agreement, and includes the Appendices attached hereto, the Supply and Quality Documentation and any and all amendments of any of the foregoing hereafter signed by the Parties with reference to this Agreement and made part hereof.

CONFIDENTIAL

*CONFIDENTIAL TREATMENT REQUESTED.

"Applicable Law" means all applicable laws, rules and regulations (whether federal, state or local) that may be in effect from time to time, including current Good Clinical Practices (GCP), Good Laboratory Practices (GLP) and Good Manufacturing Practices (GMP).

"Arbitration Matter" means any disputed matter that relates to or arises out of the validity, interpretation or construction of, or the compliance with or breach of, this Agreement; *provided that* such disputed matter has been considered, but not resolved, by the Executive Officers as set forth in Section 13.3. For clarity, no Publication Dispute, or any matter requiring mutual agreement of both Parties shall be an Arbitration Matter.

"BMS Class Drug" means (i) the BMS Study Drug and (ii) any other antibodies that are designed to selectively bind to PD-1 or PD-L1.

"BMS Indemnitees" shall have the meaning set forth in Section 11.2.

"*BMS Independent Patent Rights*" means any Patent Rights Controlled by BMS (or its Affiliates) (a) as of the Effective Date or (b) during the Term the subject matter of which was conceived or first reduced to practice through activities other than those performed pursuant to this Agreement, in each case of (a) or (b) that Cover the use (whether alone or in combination with other agents), manufacture, formulation or composition of matter of the BMS Study Drug.

"BMS Regulatory Documentation" means any Regulatory Documentation pertaining to the BMS Study Drug that exists as of the Effective Date or that is created during the Term through efforts outside this Agreement.

"BMS Study Data" shall have the meaning set forth in Section 8.2.

"BMS Study Drug" means BMS's proprietary anti-PD-1 monoclonal antibody product known as Opdivo® (nivolumab).

"BMS Study Invention" means any Invention that pertains to (a) the composition of matter of any BMS Class Drug (and not any Recipient Class Drug), (b) method of manufacture or formulation of any BMS Class Drug (and not any Recipient Class Drug) as a Single Agent Compound, and/or (c) a method of use of any BMS Class Drug (and not any Recipient Class Drug) as a monotherapy or as used with other agents, antibodies or compounds (other than an Invention pertaining, whether generically or specifically, to the composition of matter, method of manufacture or formulation, or a method of use of both a BMS Class Drug and a Recipient Class Drug).

"*BMS Study Patent Rights*" means any Patent Rights that Cover any BMS Study Invention (and not a Recipient Study Invention or Combined Therapy Invention), excluding BMS Independent Patent Rights and BMS Technology. For avoidance of doubt, any Patent Rights that cover both (a) a BMS Study Invention and (b) any other type of Invention is included within the Combined Therapy Patent Rights.

"*BMS Technology*" means all Technology Controlled by BMS (or its Affiliates) as of the Effective Date or during the Term created through efforts outside of this Agreement related to the BMS Study Drug or the Combined Therapy and necessary for the conduct of the Combined Therapy Clinical Trial. For clarity, BMS Technology does not include (a) Inventions, (b) Study Data, or (c) Combined Therapy Clinical Trial Regulatory Documentation.

"Breaching Party" shall have the meaning set forth in Section 12.2(a).

"Business Day" means a day other than Saturday, Sunday or any day on which commercial banks located in New York, NY are authorized or obligated by Applicable Law to close.

CONFIDENTIAL

*CONFIDENTIAL TREATMENT REQUESTED.

"CDA" shall have the meaning set forth in Section 9.1(a).

"*Clinical Hold*" means that (a) the FDA has issued an order to a Party pursuant to 21 CFR §312.42 to delay a proposed clinical investigation or to suspend an ongoing clinical investigation of the Combined Therapy or such Party's Single Agent Compound in the United States or (b) a Regulatory Authority other than the FDA has issued an equivalent order to that set forth in (a) in any other country or group of countries.

"Combined Therapy" means a therapy using the Recipient Study Drug and the BMS Study Drug in combination, with or without another agent.

"*Combined Therapy Clinical Trial*" means the human clinical trial using the Recipient Study Drug and the BMS Study Drug, which will be conducted under the Recipient's protocol (said, protocol, as it may be amended from time to time in accordance with this Agreement, the "*Protocol*") and is incorporated herein by reference. A draft Protocol summary as of the Effective Date is attached as <u>Appendix A</u> hereto. The draft Protocol shall be jointly agreed by the Parties as set forth in Section 2.1(a).

"Combined Therapy IND" shall have the meaning set forth in Section 2.1(b).

"Combined Therapy Invention" means an Invention that is not a Recipient Study Invention or a BMS Study Invention.

"Combined Therapy Patent Right(s)" means any Patent Rights that Cover any Combined Therapy Invention or Combined Therapy Study Data. For clarity, "Combined Therapy Patent Right(s)" do not include any BMS Independent Patent Rights and Recipient Independent Patent Rights.

"*Combined Therapy Clinical Trial Regulatory Documentation*" means any Regulatory Documentation to be submitted for the conduct of the Combined Therapy Clinical Trial, but excluding (a) any Recipient Regulatory Documentation and (b) any BMS Regulatory Documentation.

"Combined Therapy Study Data" shall have the meaning set forth in Section 8.2.

"Commercially Reasonable Efforts" means, with respect to a Party, the level of effort and resources normally devoted by such Party to conduct a clinical trial for a biopharmaceutical product or compound that is owned by it or to which it has rights, which is of similar market potential, profit potential or strategic value and at a similar stage in its development or product life based on conditions then prevailing.

"Confidential Information" shall have the meaning set forth in Section 9.1(a).

"*Control*" or "*Controlled*" means, with respect to particular information or intellectual property, that the applicable Party owns or has a license to such information or intellectual property and has the ability to grant a right, license or sublicense to the other Party as provided for herein without violating the terms of any agreement or other arrangement with any Third Party.

"*Cover*" means, with respect to a Patent Right, that, but for rights granted to a Person under such Patent Right, the practice by such Person of an invention described in such Patent Right would infringe a claim included in such Patent Right, or in the case of a Patent Right that is a patent application, would infringe a claim in such patent application if it were to issue as a patent. "*Covered*" or "*Covering*" shall have correlative meanings.

"*CRO*" means any Third Party contract research organization used to conduct the Combined Therapy Clinical Trial, including laboratories and Third Parties used to maintain the safety database from the Combined Therapy Clinical Trial, but, for clarity, excluding clinical trial sites and any Third Parties who are individuals.

CONFIDENTIAL

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"Date of First Receipt" means, with respect to a Party, the date on which any employee of such Party, its Affiliates or its Third Party subcontractors first becomes aware of safety-related information.

"Designated Clinical Contact" shall have the meaning set forth in Section 2.3.

"Designated Supply Contact" shall have the meaning set forth in Section 4.7.

"Dispute" shall have the meaning set forth in Section 13.3(b).

"*Effective Date*" shall have the meaning set forth in the preamble to this Agreement.

"Executive Officers" means the Chief Executive Officer of the Recipient and the Head of Oncology Development of BMS (or their respective designees).

"FDA" means the United States Food and Drug Administration, or any successor agency having the same or similar authority.

"Filing Party" shall have the meaning set forth in Section 6.1(c).

"Global Safety Database" means the database containing Adverse Events, Serious Adverse Events, Serious Adverse Drug Reactions and pregnancy reports for the Combined Therapy, and shall be the authoritative data source for regulatory reporting and responding to regulatory queries with respect to the Combined Therapy Clinical Trial.

"Good Clinical Practices" or "GCP" means, as to the United States and the European Union, applicable good clinical practices as in effect in the United States and the European Union, respectively, during the Term and, with respect to any other jurisdiction, clinical practices equivalent to good clinical practices as then in effect in the United States or the European Union.

"Good Laboratory Practices" or "GLP" means, as to the United States and the European Union, applicable good laboratory practices as in effect in the United States and the European Union, respectively, during the Term and, with respect to any other jurisdiction, laboratory practices equivalent to good laboratory practices as then in effect in the United States or the European Union.

"Good Manufacturing Practices" or "GMP" means, as to the United States and the European Union, applicable good manufacturing practices as in effect in the United States and the European Union, respectively, during the Term and, with respect to any other jurisdiction, manufacturing practices equivalent to good manufacturing practices as then in effect in the United States or the European Union.

"*ICF*" shall have the meaning set forth in Section 5.1(f).

"IND" means (a) an Investigational New Drug Application as defined in the United States Food, Drug and Cosmetic Act, as amended, and regulations promulgated thereunder, or any successor application or procedure required to initiate clinical testing of a drug in humans in the United States, (b) a counterpart of such an Investigational New Drug Application that is required in any other country before beginning clinical testing of a drug in humans in such country, including, for clarity, a *"Clinical Trial Application"* in the European Union, and (c) all supplements and amendments to any of the foregoing.

"*Indemnify*" shall have the meaning set forth in Section 11.1.

CONFIDENTIAL

*CONFIDENTIAL TREATMENT REQUESTED.

"*Infringe*" and "*Infringement*" means any alleged or threatened (in writing) infringement, or misappropriation by a Third Party, of any Patent Rights.

"*Invention*" means any invention or Technology, whether or not patentable, that is made, conceived, or first actually reduced to practice after the Effective Date by, for or on behalf of a Party, or by, for or on behalf of the Parties together (including by a Third Party in the performance of the Combined Therapy Clinical Trial), (a) in relation to the Combined Therapy Clinical Trial to be conducted under this Agreement or (b) by or resulting from the use of Study Data, but excluding in each case any Study Data itself.

"IRB" means an Investigational Review Board or Ethics Committee (or similar body in a given country).

"Licensee" shall have the meaning set forth in Section 13.10(b).

"Losses" shall have the meaning set forth in Section 11.1.

"*Manufacture*" or "*Manufacturing*" means manufacturing, processing, formulating, packaging, labeling, holding (including storage), and quality control testing of a Single Agent Compound or the Combined Therapy, in each case so as to be suitable for use in the Combined Therapy Clinical Trial under Applicable Law.

"*Material Safety Issue*" means a Party's good faith belief that there is an unacceptable risk for harm in humans based upon: (a) pre-clinical safety data, including data from animal toxicology studies, or (b) the observation of Serious Adverse Events in humans after the Recipient Study Drug or the BMS Study Drug, either as a Single Agent Compound or in combination with another pharmaceutical agent (including as the Combined Therapy), has been administered to or taken by humans, such as during the Combined Therapy Clinical Trial.

"*NDA*" means (a) any new drug application or biologics license application filed with the FDA, or any successor application or procedure required to introduce a drug or biologic into commerce in the United States, (b) a counterpart of such a new drug application or biologics license application that is required in any other country before beginning the commercialization of a drug or a biologic in humans in such country, and (c) all supplements and amendments to any of the foregoing.

"Non-Breaching Party" shall have the meaning set forth in Section 12.2(a).

"Officials" shall have the meaning set forth in Section 10.9.

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[]*
[]*
"Operational Matters" shall have the meaning set forth in Section 5.1.
"Party" or "Parties" shall have the meaning set forth in the preamble to this Agreement.

"*Patent Rights*" means any (a) United States or foreign patents, (b) United States or foreign patent applications, including all provisional applications, substitutions, continuations-in-part, divisions, renewals, and all patents granted thereon, (c) United States or foreign patents-of-addition, reissues, reexaminations (including *ex parte* reexaminations, *inter partes* reviews, *inter partes* reexaminations, post grant reviews and supplemental examinations) and extensions or restorations by existing or future extension or restoration mechanisms, including supplementary protection certificates,

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patent term extensions, or the equivalents thereof, and (d) any other form of government-issued right substantially similar to any of the foregoing.

"Payment" shall have the meaning set forth in Section 10.9.

"*Person*" means any individual, sole proprietorship, partnership, limited partnership, limited liability partnership, corporation, limited liability company, business trust, joint stock company, trust, unincorporated association, joint venture or other similar entity or organization, including a government or political subdivision, department or agency of a government.

"Personal Data" means any information relating to an identified or identifiable natural person.

"POTV" shall have the meaning set forth in Section 9.6(a).

"Protocol" shall have the meaning set forth in the definition of Combined Therapy Clinical Trial.

"Publication Dispute" shall have the meaning set forth in Section 9.5(b).

"Quarter" means a calendar quarter.

"Recipient Class Drug" means the Recipient Study Drug and any oncolytic virus derived from a potent herpes simplex virus strain expressing gibbon ape leukemia virus glycoprotein and eliciting anti-tumor activity.

"Recipient Indemnitees" shall have the meaning set forth in Section 11.1.

"*Recipient Independent Patent Rights*" means any Patent Rights Controlled by the Recipient or a Recipient Affiliate (a) as of the Effective Date or (b) during the Term the subject matter of which was conceived or first reduced to practice through activities other than those performed pursuant to this Agreement, in each case (a) and (b) that Cover the use (either alone or in combination with other agents), manufacture, formulation or composition of matter of the Recipient Study Drug.

"Recipient Regulatory Documentation" means any Regulatory Documentation pertaining to the Recipient Study Drug that exists as of the Effective Date or that is created during the Term through efforts outside this Agreement.

"Recipient Study Data" shall have the meaning set forth in Section 8.2.

"Recipient Study Drug" means the Recipient's proprietary oncolytic virus known as RP-1.

"*Recipient Study Invention*" means any Invention that pertains to (a) the composition of matter of any Recipient Class Drug (and not any BMS Class Drug), (b) method of manufacture or formulation of any Recipient Class Drug (and not any BMS Class Drug) as a Single Agent Compound, or (c) a method of use of the Recipient Class Drug (and not any BMS Class Drug) as a monotherapy or as used in combination with other agents, antibodies or compounds (other than Invention pertaining, whether generically or specifically, to the composition of matter, method of manufacture, formulation or a method of use of both a BMS Class Drug and a Recipient Class Drug.

"*Recipient Study Patent Rights*" means any Patent Rights that Cover any Recipient Study Invention (and not a BMS Study Invention or a Combined Therapy Invention), excluding Recipient Independent Patent Rights and Recipient Technology. For avoidance of doubt, any Patent Rights that cover both (a) a Recipient Study Invention and (b) any other type of Invention is included within the Combined Therapy Patent Rights.

"*Recipient Technology*" means all Technology Controlled by the Recipient or a Recipient Affiliate as of the Effective Date or during the Term which is created through efforts outside of this Agreement related to the Recipient Study Drug or the Combined Therapy and necessary for the conduct of the Combined Therapy Clinical Trial. For clarity, Recipient Technology does not include (a) Inventions, (b) Study Data, or (c) Combined Therapy Clinical Trial Regulatory Documentation.

"Regulatory Authority" means the FDA or any other governmental authority outside the United States (whether supranational, national, federal, provincial and/or local) that is the counterpart to the FDA, including the European Medicines Agency for the European Union.

"*Regulatory Documentation*" means, with respect to a Party's Single Agent Compound, all submissions to Regulatory Authorities in connection with the development of such Single Agent Compound, as applicable, including all INDs and amendments thereto, NDAs and amendments thereto, drug master files, correspondence with regulatory agencies, periodic safety update reports, adverse event files, complaint files, inspection reports and manufacturing records, in each case together with all supporting documents (including documents that include clinical data).

"*Results*" shall have the meaning set forth in Section 9.5(b).

"*Right of Cross-Reference*" means, with regard to a Party, allowing the applicable Regulatory Authority in a country to have access to relevant information (by cross-reference, incorporation by reference or otherwise) contained in Regulatory Documentation (and any data contained therein) filed with such Regulatory Authority with respect to a Party's Single Agent Compound (and, in the case of BMS, the Right to Cross-Reference the Combined Therapy IND), only to the extent necessary for the conduct of the Combined Therapy Clinical Trial in such country or as otherwise expressly permitted or required under this Agreement to enable a Party to exercise its rights or perform its obligations hereunder, and, except as to information contained in the Combined Therapy IND pertaining to the Combined Therapy, without the disclosure of such information to such Party.

"*Safety Issue*" means any information suggesting an emerging safety concern or possible change in the risk-benefit balance for a drug, including information on a possible causal relationship between an Adverse Event and a drug, the relationship being unknown or incompletely documented previously.

"*Safety Signal*" means information arising from one or multiple sources, including observations and experiments, which suggests a new potentially causal association, or a new aspect of a known association between an intervention and an event or set of related events, either adverse or beneficial, that is judged to be of sufficient likelihood to justify verificatory action.

"*Samples*" means biological specimens collected from Combined Therapy Clinical Trial study subjects (including fresh and/or archived tumor samples, serum, peripheral blood mononuclear cells, plasma, and whole blood for RNA and DNA sample isolation).

"Shortage" shall have meaning set forth in Section 4.5.

"*Single Agent Compound*" or "*Compound*" means, with respect to (a) the Recipient, the Recipient Study Drug, as monotherapy, and (b) BMS, the BMS Study Drug, as monotherapy.

"Sponsor" means an applicant or holder of clinical studies applications/notifications.

"Study Data" shall have the meaning set forth in Section 8.1.

"Sunshine Laws" shall have the meaning set forth in Section 9.6(c).

"Supply and Quality Documentation" shall have the meaning set forth in Section 4.3.

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"Technology" means information, inventions, discoveries, trade secrets, knowledge, technology, methods, processes, practices, formulae, instructions, skills, techniques, procedures, experiences, ideas, technical assistance, designs, drawings, assembly procedures, computer programs, specifications, data and results not generally known to the public (including biological, chemical, pharmacological, toxicological, pharmaceutical, physical and analytical, pre-clinical, clinical, safety, manufacturing and quality control data and know-how, including study designs and protocols), in all cases, whether or not patentable, in written, electronic or any other form now known or hereafter developed and materials, including Regulatory Documentation.

"Term" shall have the meaning set forth in Section 12.1.

"Territory" means the United States, including Puerto Rico, and the European Union (including the United Kingdom, whether or not an EU member state). For clarity, the Territory excludes the []*.

"Third Party" means any Person or entity other than the Recipient and BMS and their respective Affiliates.

"Third Party Claim" shall have the meaning set forth in Section 11.1.

"*Third Party License Payments*" means any payments (e.g., upfront payments, milestones, royalties) due to any Third Party under license agreements or other written agreements granting rights to intellectual property owned or controlled by such Third Party to the extent that such rights are necessary for (a) the making, using or importing of a Party's Single Agent Compound for the conduct of the Combined Therapy Clinical Trial, or (b) the conduct of the Combined Therapy Clinical Trial.

"TP Study Costs" shall have the meaning set forth in Section 7.2.

ARTICLE 2

SCOPE

2.1 Scope.

(a) The Recipient will conduct the Combined Therapy Clinical Trial in accordance with the Protocol and the terms of this Agreement. The Parties will use good faith efforts to jointly agree on a draft Protocol within []* following the Effective Date, which shall be based on the draft Protocol summary attached as <u>Appendix A</u> hereto. The Recipient shall be solely responsible for the content of the Protocol following agreement by the Parties on the draft Protocol; *provided that*: (i) the Recipient will notify BMS of any proposed amendments to the draft Protocol agreed by the Parties (or to the final Protocol initially approved by an IRB) and the Recipient will consider any comments provided by BMS regarding the proposed amendments (it being understood that the Parties will endeavor to set forth in writing the circumstances (e.g., administrative matters) where it may be feasible for the Recipient to make specific Protocol amendments without the need for BMS to comment), and (ii) any changes to the draft Protocol agreed by the Parties (or to the final Protocol initially approved by an IRB) that pertain to the administration of the BMS Study Drug must be reviewed and expressly approved by BMS in writing or the change may not be implemented. BMS shall have []* from the date on which the Recipient provides the applicable Protocol amendment to BMS to approve or provide any comments to the Recipient concerning the proposed amendment. For clarity, Recipient shall not conduct any patient recruitment activities for, or otherwise initiate, the Combined Therapy Clinical Trial until the draft Protocol is jointly agreed by the Parties.

(b) The Combined Therapy Clinical Trial shall be conducted under a combination IND, for which the Recipient will be the sponsor of record (the "*Combined Therapy IND*") and shall be

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conducted only in the Territory. The Recipient shall be the sole holder of all legal interests in the Combined Therapy IND; *provided*, *however*, *that* the Recipient may not grant any Third Party any Right of Cross-Reference with respect to any portion of the Combined Therapy IND pertaining to BMS's Single Agent Compound for use as monotherapy or for use in combination with any molecules, agents, antibodies or compounds other than the Recipient Study Drug.

(c) BMS will make available its current package insert for the BMS Study Drug in the Territory available to the Recipient and will provide any updates thereto at the same time as the same are made publicly available.

(d) If the Recipient and BMS agree that the Recipient will require access to the investigator's brochure for the BMS Study Drug in order for the site to conduct the Combined Therapy Clinical Trial, then (i) BMS will provide the current version of its investigator brochure to the Recipient promptly and (ii) will thereafter, until the conclusion of the Combined Therapy Clinical Trial, provide to the Recipient, upon reasonable request, the latest investigator's brochure for the BMS Study Drug or any amendments thereto in accordance with BMS's customary practices for same. The Recipient shall, and shall require that any clinical trial sites for the Combined Therapy Clinical Trial shall, use any such data provided pursuant to this Section 2.1(d) solely (A) to evaluate the safety and efficacy of the BMS Study Drug and the Combined Therapy for use in Combined Therapy Clinical Trial, (B) to meet any regulatory requirements pertaining to the conduct of the Combined Therapy Clinical Trial and (C) to enable the Recipient to draft and update as necessary the investigator's brochure for the Combined Therapy Clinical Trial. The Recipient will ensure that clinical trial sites for the Combined Therapy Clinical Trial and (C) to enable the Recipient Therapy Clinical Trial are obligated to protect such information and disclosures as set forth in Article 9. The Recipient's right to use the investigator's brochure provided by BMS shall terminate upon the completion or termination of the Combined Therapy Clinical Trial and shall not be used for purposes of conducting any other clinical studies.

(e) If requested in writing by the Recipient and agreed to by BMS (such consent not to be unreasonably withheld), BMS shall provide a Right of Cross-Reference as needed to its existing Regulatory Documentation for BMS's Single Agent Compound for those countries in the Territory where the Combined Therapy Clinical Trial will be conducted solely as necessary to allow the Combined Therapy Clinical Trial to be conducted under the Combined Therapy IND in an applicable country; *provided that* such Right of Cross-Reference shall terminate upon the expiration or termination of this Agreement and shall not be used for purposes of conducting any other clinical studies, except that, in the case of termination for a Material Safety Issue pursuant to Section 12.4, such Right of Cross-Reference shall remain in effect solely (i) to the extent necessary to permit the Recipient to comply with any outstanding obligations required by a Regulatory Authority and/or Applicable Law or (ii) as necessary to permit the Recipient to continue to dose subjects enrolled in the Combined Therapy Clinical Trial through completion of the Protocol if required by the applicable Regulatory Authority(ies) and/or Applicable Laws.

(f) If PDL-1 biomarker testing is incorporated into the Protocol, the Recipient agrees to use the commercially available []* to perform such testing.

(g) The Recipient shall refer to the applicable BMS Study identification number in all Combined Therapy Clinical Trial reports, reports of Serious Adverse Events, BMS Study Drug requests, and all other material submissions or communications to BMS relating to the Protocol.

2.2 Adverse Event Reporting.

(a) This Section 2.2 shall govern safety reporting arising from the Combined Therapy Clinical Trial. The Recipient will manage all drug safety reporting activities for the Combined Therapy Clinical Trial.

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(b) The Recipient will forward to BMS at the contact information below via fax or secure e-mail in a format to be agreed to by the Parties all fatal or life threatening SAE reports within four (4) calendar days of Date of First Receipt, all other SAE reports, reports of exposure during pregnancy (maternal and paternal) and reports of suspected transmission of an infectious agent via the BMS Study Drug or Combined Therapy within nine (9) calendars days of Date of First Receipt, in each case for the BMS Study Drug and the Combined Therapy administered in the Combined Therapy Clinical Trial.

BMS – Adverse Event Reporting Co	ntact
E-mail	[]*
Fax	[]*
Acknowledgment of ICSR	[]*
receipt:	

(c) Each Party shall collect, use and disclose Personal Data obtained in the course of performing the pharmacovigilance activities under this Section 2.2 solely for the purposes of complying with the regulatory obligations as described in this Agreement, or as otherwise required by Applicable Law or by a court order. Both Parties will use electronic, physical, and other safeguards appropriate to the nature of the information to prevent any use or disclosure of Personal Data other than as provided for by this Agreement and permitted under the ICF. Both Parties will also take reasonable precautions to protect such Personal Data from accidental, unauthorized, or unlawful alteration or destruction. Each Party will notify the other Party promptly of any accidental, unauthorized, or unlawful destruction, or disclosure of, or access of such Personal Data.

(d) The Recipient will promptly make available to BMS upon request such records that the Recipient Controls as is necessary or useful to perform medical assessment of any Adverse Event associated with the use of the BMS Study Drug or Combined Therapy reported during the Combined Therapy Clinical Trial that is forwarded to BMS under this Agreement. The Recipient will designate a single point of contact within its organization (and will provide to BMS the email address of such point of contact prior to the start of the Combined Therapy Clinical Trial) for any pharmacovigilance-related follow-up questions that BMS would have.

(e) The Recipient shall perform case level reconciliation to confirm that BMS has received all reports required under this Agreement. The Recipient shall e-mail []* to request a reconciliation report for the Combined Therapy Clinical Trial. The Recipient shall reconcile the cases identified as being transmitted to BMS on BMS's reconciliation report and those contained in the Combined Therapy Clinical Trial database. The Recipient shall send missing case-level events to BMS Global Pharmacovigilance at []* or by fax at []*. The Recipient shall perform such reconciliation every []*, unless otherwise agreed by BMS in writing.

(f) As Sponsor, the Recipient will be responsible for submitting all applicable Individual Case Safety Report (ICSRs) and aggregate report submissions to Regulatory Authorities for the Combined Therapy Clinical Trial. The Recipient will provide BMS with the final version of any aggregate report at the time of submission. The Recipient will also submit appropriate safety letters or safety reports to study investigators, the reviewing IRB and authorized Regulatory Authorities in accordance with Applicable Law.

(g) In the event that BMS produces any Development Safety Update Report ("*DSUR*") in respect to the BMS Study Drug, BMS will provide to the Recipient upon request, and for the duration of the Combined Therapy Clinical Trial, copies of the executive summary and any line listings of Serious Adverse Drug Reactions extracted from the final DSUR for information purposes only and to assist the Recipient in generation of their own clinical trial aggregate report, where applicable. The Recipient agrees not to forward such BMS DSUR sections to any Third Party, except to its Affiliates, consultants, advisors and contractors under obligations of confidentiality for generation of such a clinical trial aggregate

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report or as otherwise permitted with respect to BMS Confidential Information under Section 9.3(b), (d), (e), and (f).

(h) If the Recipient determines there is a significant Safety Issue or significant Safety Signals arising in a clinical trial that may be associated with the BMS Study Drug or Combined Therapy, the Recipient will disclose such information to BMS promptly after such determination.

(i) BMS will ensure that any urgent Safety Issues or Safety Signals relating to the BMS Study Drug will be communicated to the Recipient promptly after such determination.

2.3 Clinical Study Designated Contact. Each Party will designate an employee within its organization (the "*Designated Clinical Contact*") who will coordinate and/or facilitate:

(a) the review of Protocol amendments submitted by the Recipient for BMS approval and with whom comments thereon may be discussed;

- (b) any BMS clinical and regulatory responsibilities and communications regarding the Combined Therapy Clinical Trial;
- (c) internal BMS review of any document or regulatory communication and the provision of any BMS comments; and
- (d) discussion of any other topics or issues relating to the Combined Therapy Clinical Trial requested by the Recipient or BMS.

2.4 Conduct. Each Party shall use Commercially Reasonable Efforts to (a) perform and fulfill its respective activities under the Combined Therapy Clinical Trial and this Agreement on a timely basis and in an effective manner consistent with prevailing standards, (b) supply the quantities of its Compound in accordance with Article 4 as needed to conduct the Combined Therapy Clinical Trial on a timely basis, and, in the case of the Recipient, package and deliver same to study sites on a timely basis, and (c) in the case of the Recipient, conduct and complete the Combined Therapy Clinical Trial on a timely basis in accordance with the Protocol and Third Party agreements relating thereto, and provide sufficient resources, funding and personnel to conduct and perform the Combined Therapy Clinical Trial on a timely basis in accordance with the Protocol for same and the terms of this Agreement. Each Party shall perform its duties for the Combined Therapy Clinical Trial in accordance with Applicable Law, including GCP, GLP and GMP as applicable.

ARTICLE 3

LICENSE GRANTS

3.1 Grant by BMS. Subject to the terms of this Agreement, BMS hereby grants, and shall cause its Affiliates to grant, to the Recipient a nonexclusive, non-transferable, royalty-free license (with the right to sublicense solely pursuant to the terms of and subject to the limitations of Section 3.2) under the BMS Independent Patent Rights and BMS Technology to use the BMS Study Drug solely within the Territory and solely to the extent necessary to discharge the Recipient's obligations under this Agreement with respect to the conduct of the Combined Therapy Clinical Trial in the Territory.

3.2 Sublicensing.

(a) The Recipient shall have the right to grant sublicenses under the licenses granted to it under Section 3.1, to Affiliates and to Third Parties, if required for an Affiliate or a Third Party to perform its duties with respect to the conduct of the Combined Therapy Clinical Trial, solely as necessary

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to assist the Recipient in carrying out its responsibilities with respect to the Combined Therapy Clinical Trial.

(b) With regard to any such sublicenses permitted and made under this Agreement, (i) the sublicensees, except Affiliates (so long as they remain Affiliates of a Party), shall be subject to written agreements that bind such sublicensees to obligations that are consistent with a Party's obligations under this Agreement including confidentiality and non-use provisions no less restrictive than those set forth in herein, and provisions regarding intellectual property that ensure that the Parties will have the rights provided under this Agreement to any intellectual property relating to their Single Agent Compound and/or the Combined Therapy created by such sublicensee, (ii) each Party shall provide written notice to the other Party of any such sublicense (and obtain approval for sublicenses to Third Parties other than clinical trial sites); and (c) the licensing Party shall remain liable to the other Party for all actions of the sublicensing Party's sublicensees.

3.3 No Implied Licenses. Unless and except as specifically set forth in this Agreement, neither Party shall acquire any license or other intellectual property interest, by implication or otherwise, in any intellectual property of the other Party, including Confidential Information disclosed to it under this Agreement or under any Patent Rights Controlled by the other Party or its Affiliates.

ARTICLE 4

MANUFACTURE AND SUPPLY

4.1 Recipient Study Drug Manufacture and Supply.

(a) The Recipient shall be responsible, at its sole costs and expense, for manufacturing, packaging and labeling (or having manufactured, packaged or labeled) GMP-grade quantities of the Recipient Study Drug, as well as obtaining any other drug (other than the BMS Study Drug provided by BMS pursuant to Section 4.2) required for the conduct of the Combined Therapy Clinical Trial, and shall package and label if and as required by the Protocol and/or applicable Regulatory Authorities all drugs (including the BMS Study Drug) used in the Combined Therapy Clinical Trial, on a timely basis and in accordance with applicable specifications as required for the conduct of the Combined Therapy Clinical Trial. The Recipient Study Drug shall be manufactured in accordance with Applicable Law (including GMP) and shall be of similar quality to the Recipient Study Drug used by the Recipient for its other clinical trials of the Recipient Study Drug.

(b) The Recipient shall provide BMS with prompt notice of any Manufacturing and supply issues with respect to the Recipient Study Drug, or any defects or manufacturing problems identified with respect to the BMS Study Drug supplied to Recipient, that may adversely impact the conduct or timelines of the Combined Therapy Clinical Trial.

4.2 BMS Study Drug.

(a) Manufacture and Supply. BMS shall Manufacture or have Manufactured the BMS Study Drug in reasonable quantities needed, and at the points in time as agreed to by the Parties, for the Combined Therapy Clinical Trial, and shall supply such BMS Study Drug as either commercially labeled or unlabeled vials to the Recipient or its designee for use solely in the Combined Therapy Clinical Trial. The Recipient will at its sole expense, package and label the BMS Study Drug for use in the Combined Therapy Clinical Trial to the extent necessary. The cost of Manufacture and supply (including shipping, taxes and duty, if applicable) of the BMS Study Drug for the Combined Therapy Clinical Trial shall be borne solely by BMS, and BMS shall bear the risk of loss for such quantities of BMS Study Drug until delivery of such quantities of BMS Study Drug to the Recipient or its designee. BMS shall also be responsible for the payment of any Third Party License Payments that may be due based on the manufacture,

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supply and use of the BMS Study Drug used in the Combined Therapy Clinical Trial. The BMS Study Drug shall be manufactured in accordance with Applicable Law (including GMP) and shall be of similar quality to the BMS Study Drug used by BMS for its other clinical trials of the BMS Study Drug. BMS shall deliver certificates of analysis, and any other documents specified in the Supply and Quality Documentation, including such documentation as is necessary to allow the Recipient to compare the BMS Study Drug certificate of analysis to the BMS Study Drug specifications. Pursuant to the Supply and Quality Documentation, BMS shall be responsible for the regulatory compliance of the quality of the BMS Study Drug at the time the BMS Study Drug is delivered to the Recipient with the regulatory filings in the countries in the Territory where the Combined Therapy Clinical Trial will be performed. Subject to Section 4.4, the Parties shall cooperate in accordance with Applicable Law to minimize indirect taxes (such as value added tax, sales tax, consumption tax and other similar taxes) relating to the BMS Study Drug in connection with this Agreement.

(b) Use of BMS Study Drug Supplied by BMS to the Recipient. The Recipient shall use the quantities of BMS Study Drug supplied to it under this Agreement solely as necessary for, and in accordance with, this Agreement and the Protocol, and for no other purpose, including as a reagent or tool to facilitate its internal research efforts, for any commercial purpose, or for other clinical or non-clinical research unrelated to the Combined Therapy Clinical Trial. Except as may be required or expressly permitted by the Protocol or the Supply and Quality Documentation, the Recipient shall not perform, and shall not allow any Third Party to perform, any analytical testing of the quantities of BMS Study Drug supplied to it under this Agreement. If Study Drug supplied by BMS is lost, damaged, destroyed or becomes unable to comply with applicable specifications while under the control of the Recipient or any of its (sub)contractors, including common carriers and clinical study sites contracted by the Recipient, BMS shall not be obligated to replace same, and if BMS does elect to do so, BMS may elect to charge the Recipient a reasonable replacement cost to replace same.

4.3 Supply and Quality Documentation. BMS shall supply the BMS Study Drug to the Recipient in accordance with such supply and quality addenda or agreement(s) as the Parties may agree (the "*Supply and Quality Documentation*"). The Parties shall finalize and execute the Supply and Quality Documentation within []* of the Effective Date, but in no event later than the date on which the first shipment of the BMS Study Drug is supplied for use in the Combined Therapy Clinical Trial. The Supply and Quality Documentation shall outline the additional roles and responsibilities relative to the quality of BMS Study Drug in support of the Combined Therapy Clinical Trial. It shall include the responsibility for quality elements as well as exchanged GMP documents and certifications required to release the BMS Study Drug for the Combined Therapy Clinical Trial. In addition, the Supply and Quality Documentation shall detail the documentation required for each shipment of BMS Study Drug supplied to the Recipient or its designee for use in the Combined Therapy Clinical Trial.

4.4 Supply Forecast. Estimated supply and delivery details will be outlined in the Supply and Quality Documentation and will be updated by the Parties by mutual agreement (which agreement can be effected by the Parties' Designated Supply contacts and without need for an amendment to this Agreement) based on the actual enrollment. The Recipient will promptly inform BMS of any change in its requirements, and BMS will endeavor to accommodate any change in the supply quantities requested by the Recipient so long as it does not unduly disrupt BMS's ongoing business activities.

4.5 Shortages. BMS shall provide the Recipient with prompt notice of any Manufacturing and supply issues with respect to the BMS Study Drug that may adversely impact the conduct or timelines of the Combined Therapy Clinical Trial. In the event of a supply interruption or shortage of BMS Study Drug as determined by BMS pursuant to its internal processes and policies (a "*Shortage*"), such that BMS reasonably believes that it will not be able to fulfill its supply obligations under this Agreement, BMS will provide prompt written notice thereof to the Recipient (including the quantity of BMS Study Drug that BMS reasonably estimates it will be able to supply) and, upon request, the Parties will promptly discuss such situation (including how the quantities of BMS Study Drug that BMS is able to supply under this

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Agreement will be allocated within the Combined Therapy Clinical Trial). Notwithstanding anything to the contrary contained herein, in the event of a Shortage of the BMS Study Drug, BMS will have sole discretion, subject to Applicable Law, to determine the quantity of BMS Study Drug it will be able to supply as a result of such Shortage; provided, however, that BMS shall consider in good faith the needs of patients who are actively being treated with BMS Study Drug, including Combined Therapy Clinical Trial patients, in making such determination. BMS will not be deemed to be in breach of this Agreement for failure to supply any other quantities of BMS Study Drug hereunder as a result of a Shortage. Any such allocation of the BMS Study Drug in accordance with this Section 4.5 will be the Recipient's exclusive remedy with respect to a Shortage.

4.6 Customs Valuation. The Recipient will provide BMS in writing with a list of each country in which it proposes to conduct the Combined Therapy Clinical Trial prior to execution of any site agreement or CRO agreement for that country. During the conduct of the Combined Therapy Clinical Trial, the Recipient will send in writing any changes to the list of participating countries to BMS one month prior to the end of each Quarter. If no changes are sent to BMS will provide the Recipient with country-specific customs valuations initially for the BMS Study Drug prior to initiation of the Combined Therapy Clinical Trial and at the end of each Quarter during the conduct of the Combined Therapy Clinical Trial. The Recipient will use the BMS provided values for the import/export process to the listed participating countries and not make any change to such valuations without BMS's prior written consent.

4.7 **Designated Supply Contact.** Each Party will designate an individual (the "*Designated Supply Contact*") that a Party may contact to assist with coordinating supplies and facilitating the resolution of any issues or concerns arising in connection with the supply of the BMS Study Drug for use in the Combined Therapy Clinical Trial.

ARTICLE 5

RESPONSIBILITIES

5.1 Specific Responsibilities of the Recipient. The Recipient shall, subject to the terms of the Protocol, applicable terms and conditions of this Agreement, and any other agreement between the Parties relating to the Combined Therapy Clinical Trial, manage and be responsible for the conduct of the Combined Therapy Clinical Trial, including timelines and contingency planning. In particular, and not in limitation of the foregoing, the Recipient shall perform (itself and/or through Third Parties, including clinical trial sites, CROs and investigators) and/or be responsible for the following (items (a) to (p) below, collectively the "*Operational Matters*") with respect to the Combined Therapy Clinical Trial:

(a) compiling, amending and filing all necessary Combined Therapy Clinical Trial Regulatory Documentation with Regulatory Authority(ies), maintaining and acting as the sponsor of record as provided in 21 CFR 312.50 (and applicable comparable ex-US laws) with responsibility, unless otherwise delegated in accordance with 21 CFR 312.52 (and applicable comparable ex-US laws), for the Combined Therapy Clinical Trial and making all required submissions to Regulatory Authorities related thereto on a timely basis;

(b) conducting clinical study start-up activities, communicating with and obtaining approval from IRBs for the Protocol and other relevant documents for the Combined Therapy Clinical Trial as applicable, as well as patient recruitment and retention activities;

(c) listing of the Combined Therapy Clinical Trial, if it is required to be listed on a public database on www.clinicaltrials.gov or other public registry in any country in which such Combined Therapy Clinical Trial is being conducted, all in accordance with Applicable Law and in accordance with its internal policies relating to clinical trial registration;

(d) providing BMS with reasonable advance notice of scheduled meetings or other pre-planned non-written communications with a Regulatory Authority and the opportunity to participate in each such meeting or other non-written communication, to the extent involving a safety, efficacy or toxicology issue relating to the Combined Therapy or the BMS Study Drug or any other matter related to the Combined Therapy or Combined Therapy Clinical Trial that it determines in its reasonable judgement could potentially have an adverse effect on the BMS Study Drug. In such case, the Recipient will provide BMS with the opportunity to review, provide comments to the Recipient within []* on, and, if inconsistent with the Protocol, approve all submissions and written correspondence with a Regulatory Authority that relates to the BMS Study Drug;

(e) provide BMS (i) a written notice to the BMS Designated Clinical Contact (via email to the email address designated by BMS) of meetings or other substantive non-written communications with a Regulatory Authority within []* of such meeting or communication, and if requested by BMS following such notice, a written summary of such meeting or communication within ten (10) days of such request, and (ii) copies of any official correspondence to or from a Regulatory Authority within []* of receipt or provision, in each case of (i) or (ii) to the extent involving a safety, efficacy or toxicology issue relating to the Combined Therapy or the BMS Study Drug or any other matter related to the Combined Therapy or Combined Therapy Clinical Trial that it determines in its reasonable judgement could potentially have an adverse effect on the BMS Study Drug, and copies of all material Combined Therapy Clinical Trial Regulatory Documentation and correspondence that relates to same within []* of submission to Regulatory Authorities;

(f) subject to the terms of this Agreement, the selection and payment of, negotiation of the terms of, contracting with, managing and overseeing compliance of its agreement by and the receipt of contract deliverables from, any CRO or vendor selected by the Recipient to assist in the performance of the Combined Therapy Clinical Trial. The Recipient shall determine and approve contract deliverables and manage contract performance, including executing site contracts, drafting and obtaining IRB approval for site informed consent forms (each an "*ICF*"), obtaining signed ICFs, monitoring plans, etc. The Recipient will be responsible for ensuring that all such contracts and ICFs: (i) do not conflict with the terms of this Agreement, (ii) allow the Recipient to provide BMS with access to and use of Study Data, Samples, and other information and documents as required pursuant to this Agreement (and in no event less than the same use rights granted to the Recipient), (iii) do not impose a new obligation, whether direct, indirect, or contingent, upon BMS that is not set forth in this Agreement, and (iv) retain each of the Parties' respective intellectual property rights in and access to the BMS Technology, BMS Independent Patent Rights, Study Data, Samples, Recipient Study Drug, BMS Study Drug and Combined Therapy consistent with this Agreement, and (vi) comply with Applicable Law;

(g) providing BMS (if requested by BMS) with copies of each final site template of the Combined Therapy Clinical Trial's ICF. The Recipient shall ensure that each ICF does not impose any financial obligation, liability, damages or other cost upon BMS with respect to any injury (including death) suffered by a Combined Therapy Clinical Trial subject whether or not resulting from the administration of the BMS Study Drug or direct a study subject to BMS to seek reimbursement for any costs or seek compensation for any injury incurred in connection with the Combined Therapy Clinical Trial;

(h) if requested by BMS, providing BMS within []* with minutes from any and all external drug safety monitoring boards for the Combined Therapy Clinical Trial after receipt by the Recipient, to the extent relating to the BMS Study Drug or the Combined Therapy;

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(i) informing and updating BMS on a []* basis (with significant issues to be communicated promptly after the Recipient becomes aware of same) regarding all Operational Matters, so that if BMS has any significant concerns or material disagreements regarding same, the matter can be discussed with the Recipient. Without limiting the foregoing, the Recipient shall inform BMS []* as to the overall Combined Therapy Clinical Trial progress, []*, and any other Combined Therapy Clinical Trial-related matters requested by BMS to the extent involving a safety, efficacy or toxicology issue relating to the Combined Therapy or the BMS Study Drug or any other matter that could have an adverse effect on the BMS Study Drug;

(j) owning and being responsible for (or appointing a Third Party to be responsible for) the maintenance of the Global Safety Database and being responsible for safety reporting, collecting, evaluating and reporting Serious Adverse Events, other safety data and any further pharmacovigilance information from the Combined Therapy Clinical Trial;

(k) analyzing the Study Data in a timely fashion and providing BMS with access to the Study Data as follows:

(i) top line data and a copy of all Clinical Study Reports (CSRs), in each case, as and when received by the Recipient's clinical management;

(ii) if requested by BMS, sharing with BMS for review and comment drafts of interim and/or final clinical trial report (and/or statistical analysis in accordance with the Protocol) from the Combined Therapy Clinical Trial;

(iii) if requested by BMS, within []* after database lock, access to those safety databases that will be used for any interim review by an external consultant (or drug safety monitoring board, if required);

(iv) if requested by BMS, within []* after database lock, access to case report forms or patient profiles for all patients in the Combined Therapy Clinical Trial;

(v) if requested by BMS, within []* of the creation of an electronic clean database for the Combined Therapy Clinical Trial, an electronic copy of the clean database (the form and format of the clean database to be reasonably acceptable to both Parties);

(vi) if requested by BMS, subject to any third party requirements, providing BMS with any programs or SAS codes to be used for any statistical analysis plan for the Combined Therapy Clinical Trial; and

(vii) (A) safety analyses, (B) new and/or changing Safety Signals and Safety Issues, (C) new and/or changing toxicology and efficacy signals, and (D) any statistical analysis, immunogenicity analysis, or bioanalysis, in each case relating to the BMS Study Drug, the Recipient Study Drug and/or the Combined Therapy, as and when the same are received by the Recipient;

(I) obtaining supplies of any co-medications, to the extent any such co-medications are required for use in the Combined Therapy Clinical Trial, and providing to BMS any information related to the Combined Therapy Clinical Trial that is provided to the manufacturer of any co-medication within []* after the provision of the information to the manufacturer;

(m) if requested by BMS, information that Recipient has available to it as of such time (and with no duty to conduct any interim analysis) regarding either (i) the pharmacokinetics and safety of the Recipient Study Drug alone or (ii) the pharmacokinetics, efficacy and safety of the Recipient Study Drug in combination with the BMS Study Drug;

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- (n) performing either directly or through third parties collection of Samples required by the Protocol;
- (o) handling and addressing inquiries from the Combined Therapy Clinical Trial subjects and investigators; and
- (**p**) such other responsibilities as may be agreed to by the Parties.

5.2 BMS Operational Responsibilities. BMS shall be responsible for the following activities:

(a) Manufacturing and supplying GMP-grade quantities of the BMS Study Drug, as further described in Article 4 above, and, where and to the extent provided in the Supply and Quality Documentation, providing necessary GMP information and documentation that enables the Recipient Qualified Person (as such term will be defined in the Supply and Quality Documentation) to release BMS Study Drug for the Combined Therapy Clinical Trial;

(b) where and to the extent provided in the Supply and Quality Documentation, providing for the release by a Qualified Person or providing the necessary documentation in support of such quality release, of the BMS Study Drug if such release is required for the Combined Therapy Clinical Trial;

(c) to the extent necessary for the conduct of the Combined Therapy Clinical Trial, providing a Right of Cross-Reference to the relevant Regulatory Documentation for the BMS Study Drug as set forth in Section 2.1(b) and/or (e), if applicable, to the BMS investigator's brochure for the BMS Study Drug (and updates thereto) as provided in Section 2.1(d); and

(d) such other responsibilities as may be agreed to by the Parties.

5.3 Other Clinical Trials. Nothing in this Agreement shall preclude either Party from conducting any other clinical trials as it may determine in its discretion, so long as it does not use or rely on the Confidential Information that is solely owned by the other Party in doing so.

5.4 Potential Subsequent Studies. During the Term, each of the Parties agrees to discuss in good faith, for a period of no longer than []*, additional Combined Therapy Clinical Trials of the BMS Study Drug with the Recipient Study Drug (and/or follow-on versions of the Recipient Study Drug). If the Parties jointly agree to conduct any such further clinical trials (each, a "*Subsequent Study*"), this Agreement and the Supply and Quality Documentation shall be amended to provide for such Subsequent Study under the terms thereof. The Parties agree to discuss whether it may be useful or desirable to include []* as part of a Subsequent Study. For clarity, no Party shall be obligated to collaborate with the other Party or agree on terms with the other Party with respect to any additional clinical trials (or other collaboration opportunities) pursuant to this Section 5.4.

ARTICLE 6

INTELLECTUAL PROPERTY

6.1 Inventions and Related Patent Rights. All rights to Inventions shall be allocated as follows:

(a) Recipient Ownership. Subject to the terms of this Agreement, all Recipient Study Inventions and Recipient Study Patent Rights shall be owned solely by the Recipient, and the Recipient will have the full right to exploit such Recipient Study Inventions and Recipient Study Patent Rights without the consent of, or any obligation to account to, BMS. BMS shall assign and hereby assigns (and shall cause its Affiliates and contractors to assign) its right, title and interest in any Recipient Study Inventions and Recipient Study Patent Rights to the Recipient. BMS shall execute such further documents and provide

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other assistance as may be reasonably requested by the Recipient to perfect the Recipient's rights in such Recipient Study Inventions and Recipient Study Patent Rights, all at the Recipient's expense. The Recipient shall have the sole right but not the obligation to prepare, file, prosecute (including any

proceedings relating to reissues, reexaminations, protests, interferences, oppositions, post-grant reviews or similar proceedings and requests for patent extensions) and maintain any Recipient Study Patent Rights at its own expense.

(b) BMS Ownership. Subject to the terms of this Agreement, all BMS Study Inventions shall be owned solely by BMS, and BMS will have the full right to exploit such BMS Study Inventions without the consent of, or any obligation to account to, the Recipient. The Recipient shall assign and hereby assigns (and shall cause its Affiliates and contractors to assign) all its right, title and interest in any BMS Study Inventions and BMS Study Patent Rights to BMS. The Recipient shall execute such further documents and provide other assistance as may be reasonably requested by BMS to perfect BMS's rights in such BMS Study Inventions and BMS Study Patent Rights, all at BMS's expense. BMS shall have the sole right but not the obligation to prepare, file, prosecute (including any proceedings relating to reissues, reexaminations, protests, interferences, oppositions, post-grant reviews or similar proceedings and requests for patent extensions) and maintain any BMS Study Patent Rights at its own expense.

(c) Combined Therapy Inventions.

(i) All Combined Therapy Inventions and Combined Therapy Patent Rights shall be jointly owned by the Parties, and either Party shall have the right to freely exploit the Combined Therapy Inventions and Combined Therapy Patent Rights, both within and outside the scope of this Agreement, without accounting or any other obligation to the other Party (except as expressly set forth in this Section 6.1(c) and Section 6.3(d) with regard to the filing, prosecution, maintenance and enforcement of Combined Therapy Patent Rights) and each Party may use, exploit and grant licenses (with right to sublicense) to Third Parties under its interest in such Combined Therapy Inventions and Combined Therapy Patent Rights. The Recipient, using outside counsel acceptable to both Parties, shall be responsible, at its sole discretion, for preparing and prosecuting Patent applications and maintaining Patents within the Combined Therapy Patent Rights. The Recipient shall keep BMS advised as to material developments and steps to be taken with respect to prosecuting any such Patent Rights and shall furnish BMS with copies of applications for such Patent Rights, amendments thereto and other related correspondence to and from patent offices, and permit BMS a reasonable opportunity to review and offer comments prior to submitting such applications and correspondence to the applicable governmental authority (and will take BMS's comments into account in preparing same). BMS shall reasonably assist and cooperate in obtaining, prosecuting and maintaining the Combined Therapy Patent Rights.

(ii) Notwithstanding the foregoing clause (i), the Recipient shall not take any position in a submission to a patent office concerning a Combined Therapy Invention that interprets the scope of a Patent Right of BMS without the prior written consent of BMS, provided that BMS has notified the Recipient in writing of the existence and scope of such BMS Patent Right. The Recipient shall be reimbursed for any costs and expenses incurred in prosecuting Combined Therapy Patent Rights and the subsequent maintenance of Combined Therapy Patent Rights by BMS such that BMS shall be responsible for []* of such costs. From time-to-time, the Recipient shall invoice BMS such amounts and BMS shall pay the Recipient such invoiced amounts within thirty (30) days after receipt of an invoice therefor.

(iii) The Parties shall discuss in good faith the countries in which the Combined Therapy Patent Rights will be filed. In case one of the two Parties decides that Combined Therapy Patent Right should not be filed or maintained in a given country (and also elects not to reimburse the other Party for []* of the costs of prosecution and maintenance of such Combined Therapy Patent Right in such country), the other Party shall have the right to file, prosecute and maintain such Combined Therapy Patent Right in such country in its own name and at its own expense upon the prior consent of the other Party, which shall not be unreasonably withheld, conditioned or delayed. In this case, the Party who decides that a Combined Therapy Patent Right should not be filed or maintained (and who also decides not to

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reimburse the other Party for its share of the costs of for a given country shall promptly assign its rights to the Combined Therapy Patent Right in said country to the Party (the "*Filing Party*") who wishes to file or maintain said Combined Therapy Patent Right in such country and the Filing Party shall grant, and hereby grants, to the other Party an irrevocable, perpetual, fully-paid, non-exclusive license, with the right to grant and authorize sublicenses, under such Combined Therapy Patent Rights to make, have made, use, sell, offer for sale, import and other exploit products and services in such country. The Party who does not wish to file or maintain a Combined Therapy Patent Right in any country shall assist in the timely provision of all documents required under national provisions to register said assignment of rights with the corresponding national authorities at the sole expenses of the Party who wishes to file or maintain a Combined Therapy Patent Right in that given country. If the Parties cannot agree with respect to the decision to file or maintain a Combined Therapy Patent Right in the parties' good faith efforts to resolve any disagreement, then either Party (whichever files first) shall have the right to file or maintain any Combined Therapy Patent Right in the names of both Parties, provided that: (i) any such Combined Therapy Patent Right shall be jointly owned by the Parties and subject to the freedom to use and operate under such Combined Therapy Patent Right as set forth in the first sentence of this Section 6.1(c); (ii) such prosecuting Party obtains the prior consent of the non-prosecuting Party, which consent shall not be unreasonably withheld or delayed, and (iii) the non-prosecuting party reimburses the prosecuting party for its []* share of the patent costs.

(d) Separation of Patent Rights. In order to more efficiently enable the prosecution and maintenance of the BMS Study Patent Rights, the Recipient Study Patent Rights and Combined Therapy Patent Rights relating to Inventions as described above, the Parties will use good faith efforts to separate BMS Study Patent Rights, the Recipient Study Patent Rights, Combined Therapy Patent Rights, BMS Independent Patent Rights and the Recipient Independent Patent Rights into separate patent filings to the extent possible and without adversely impacting such prosecution and maintenance or the scope of the protected subject matter.

6.2 Disclosure and Assignment of Inventions; Ownership of Independent Patent Rights. Each Party shall disclose promptly to the other Party in writing and on a confidential basis all Inventions, prior to any public disclosure thereof or filing of Patent Rights therefor and allowing sufficient time for comment by the other Party. In addition, each Party shall, and does hereby, assign, and shall cause its Affiliates and contractors to so assign, to the other Party, without additional compensation, such right, title and interest in and to any Inventions as well as any Patent Rights and other intellectual property rights with respect thereto, as is necessary to fully effect, as applicable, the sole ownership provided for in Sections 6.1(a) and 6.1(b) and the joint ownership provided for in Section 6.1(c). Each Party shall ensure that each of its employees and contractors conducting activities under this Agreement is under written obligation to assign all right, title and interest in and to all Inventions and Study Data and all intellectual property rights therein to such Party. Except for the license granted in Section 3.1, nothing in this Agreement shall be construed to grant or transfer to BMS any rights in the Recipient Independent Patent Rights, all of which shall be the sole and exclusive property of Recipient.

6.3 Infringement of Patent Rights by Third Parties.

(a) Notice. Each Party shall promptly notify the other Party in writing of any Infringement of Combined Therapy Patent Rights, of which its in-house patent counsel becomes aware.

(b) Infringement of Recipient Study Patent Rights. For all Infringements of Recipient Study Patent Rights anywhere in the world, the Recipient shall have the exclusive right to prosecute such Infringements as it may determine in its sole and absolute discretion, and the Recipient shall bear all related expenses and retain all related recoveries. BMS shall reasonably cooperate with the

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Recipient or its designee (to the extent BMS has relevant information arising out of this Agreement), at the Recipient's request and expense, in any such action.

(c) Infringement of BMS Study Patent Rights. For all Infringements of BMS Study Patent Rights anywhere in the world, BMS shall have the exclusive right to prosecute such Infringements as it may determine in its sole and absolute discretion, and BMS shall bear all related expenses and retain all related recoveries. The Recipient shall reasonably cooperate with BMS or its designee (to the extent that the Recipient has relevant information arising out of this Agreement), at BMS's request and expense, in any such action.

(d) Infringement of Combined Therapy Patent Rights.

(i) With respect to Infringements of Combined Therapy Patent Rights, the Parties shall mutually agree as to whether to bring an enforcement action to seek the removal or prevention of such Infringements and damages therefor and, if so, which Party shall bring such action, with any costs and expenses relating thereto to be allocated in accordance with Section 6.3(d)(ii).

(ii) Regardless of which Party brings an enforcement action pursuant to Section 6.3(d)(i) or whether the Parties reach agreement to initiate such an enforcement action, the other Party hereby agrees to cooperate reasonably in any such action, including, if required, by bringing a legal action, furnishing a power of attorney or jointing as a plaintiff to such a legal action. If the Parties mutually agree to bring an enforcement action, BMS shall be responsible for []*, and the Recipient shall be responsible for []*, of the reasonable and verifiable costs and expenses incurred in connection with any such action. If either Party recovers monetary damages from any Third Party in an action agreed to by the Parties, such recovery shall be allocated first to the reimbursement of any actual, unreimbursed costs and expenses incurred by the Parties in such litigation (including, for this purpose, a reasonable allocation of expenses of internal counsel) pro rata in accordance with the aggregate amounts spent by both Parties, and any remaining amounts shall be split []* to the Recipient and []* to BMS, unless the Parties agree in writing to a different allocation. If the Party in connection with such action and shall reimburse the other Party for the costs the other Party incurs for the assistance and cooperation requested by such Party and (B) the Party initiating such enforcement action, and shall reimburse the other Party for the costs the other Party.

6.4 Infringement of Third Party Rights.

(a) Notice. If the activities relating to the Combined Therapy Clinical Trial become the subject of a claim of infringement of a patent, copyright or other proprietary right by a Third Party anywhere in the world, the Party first having notice of the claim shall promptly notify the other Party and, without regard to which Party is charged with said infringement and the venue of such claim, the Parties shall promptly confer to discuss the claim.

(b) Defense. If both Parties are charged with infringement pursuant to a claim described in Section 6.4(a), each Party shall have the right to defend itself against such claim and the Parties shall discuss in good faith defending such claim jointly. If only one Party is charged with infringement, such Party will have the first right but not the obligation to defend such claim. If the charged Party does not commence actions to defend such claim within thirty (30) calendar days after request by the other Party to do so, then the other Party shall have the right, but not the obligation, to defend any such claim to the extent such claim pertains to the other Party's Compound. In any event, the non-defending Party shall reasonably cooperate with the Party conducting the defense of the claim and shall have the right to participate with separate counsel at its own expense, and the defending Party shall consider comments and

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suggestions on strategy for defending the action by the non-defending Party in good faith. The Party defending the claim shall bear the cost and expenses of the defense of any such Third Party infringement claim and shall have sole rights to any recovery. If the Parties jointly defend the claim, the Recipient shall bear []*, and BMS shall bear []* of any costs and expenses of the defense of any such Third Party infringement claim; *provided*, *however*, *that*, notwithstanding the foregoing, if the claim relates solely to one Party's Compound, such Party will bear one hundred percent (100%) of the costs and expenses of the defense of such claim and shall have the sole right, but not the obligation, to defend, settle and otherwise handle the disposition of such claim. Neither Party shall enter into any settlement concerning activities under this Agreement or the Combined Therapy that affects the other Party's rights under this Agreement or imposes any obligations on the other Party, including any admissions of wrongdoing on behalf of the other Party, without such other Party's prior written consent, not to be unreasonably withheld or delayed, except that a Party may settle any claim that solely relates to its Compound without the consent of the other Party as long as such other Party's rights under this Agreement are not adversely impacted (in which case, it will obtain such other Party's prior written consent, not to be unreasonably withheld or delayed). If any claim described in this Section 6.4(b) is subject to a Party's indemnification obligations under Article 11, then Article 11 shall govern such claim and not this Section 6.4(b).

6.5 Combined Therapy Clinical Trial Regulatory Documentation. Subject to the license and other rights granted by each Party to the other Party pursuant to this Agreement, the Recipient shall solely own all right, title and interest in and to the Combined Therapy Clinical Trial Regulatory Documentation; *provided, however, that* BMS shall retain sole and exclusive ownership of any BMS Regulatory Documentation that is submitted with or referenced in the Combined Therapy Clinical Trial Regulatory Documentation and that the Recipient shall retain sole and exclusive ownership of any

Recipient Regulatory Documentation that is submitted with or referenced in the Combined Therapy Clinical Trial Regulatory Documentation. This Section 6.5 is without limitation of any other disclosure obligations under this Agreement.

6.6 No Other Use. Except as expressly provided in Section 6.1, the Recipient agrees not to make or file any Patent Rights application based on or containing BMS Confidential Information, and to give no assistance to any Third Party for such application without BMS's prior written authorization, and BMS agrees not to make or file any Patent Rights application based on or containing the Recipient's Confidential Information, and to give no assistance to any Third Party for such application, and to give no assistance to any Third Party for such application without the Recipient's prior written authorization.

6.7 Joint Research Agreement. The Parties acknowledge and agree that this Agreement is a "joint research agreement" as defined in 35 USC § 100 (h).

ARTICLE 7

COSTS AND EXPENSES

7.1 Manufacturing and IP Costs. Expenses incurred as described in Article 4 (regarding Manufacturing and Supply) and Article 6 (regarding Intellectual Property) shall be borne or shared by the Parties as provided in such Articles.

7.2 TP Study Costs. For all expenses (other than those set forth in section 7.1) that are directly attributable or reasonably allocable to the conduct of the Combined Therapy Clinical Trial: (a) the Recipient will solely bear all out-of-pocket costs reasonably incurred by the Recipient (or by BMS pursuant to the following sentence) to Third Parties (including to CROs, laboratories and clinical sites/IRBs) in connection with the performance of the Combined Therapy Clinical Trial ("*TP Study Costs*"), and (b) each Party shall

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be solely responsible for all of its own internal costs (including costs of individual independent contractors) incurred by such Party or any of its Affiliates. It is not expected that BMS will incur any TP Study Costs; however, in the event BMS should incur any TP Study Costs in connection with the conduct of the Combined Therapy Clinical Trial as contemplated by the budget therefor or as previously agreed to in writing by the Parties, the Recipient will reimburse BMS for same on a []* following submission of an invoice therefor and appropriate supporting documentation.

7.3 Third Party License Payments. If the conduct of the Combined Therapy Clinical Trial requires a Third Party License Payment with respect to the manufacture, supply and use of the BMS Study Drug used in the Combined Therapy Clinical Trial, then BMS shall be responsible for the payment of any such Third Party License Payment. If the conduct of the Combined Therapy Clinical Trial requires a Third Party License Payment with respect to the manufacture, supply and use of the Recipient Study Drug used in the Combined Therapy Clinical Trial, then Recipient shall be responsible for the payment of any such Third Party License Payment.

ARTICLE 8

RECORDS AND STUDY DATA

8.1 Records. Each Party shall maintain complete and accurate records of all work conducted with respect to the Combined Therapy Clinical Trial and of all results, information, data, data analyses, reports, records, methods, processes, practices, formulae, instructions, skills, techniques, procedures, experiences and developments made by or provided to either Party, or by the Parties together, in the course of such Party(ies)' efforts with respect to the Combined Therapy Clinical Trial (including any statistical analysis plan and any bioanalysis plan to be conducted pursuant to the Protocol or otherwise agreed to by the Parties) (such results, information, data, data analyses, reports, case report forms, adverse event reports, trial records, methods, processes, practices, formulae, instructions, skills, techniques, procedures, experiences, developments, and the Protocol referred to as the "*Study Data*"). Such records shall fully and properly reflect all work done and results achieved in the performance of the Combined Therapy Clinical Trial in sufficient detail and in good scientific manner appropriate for patent and regulatory purposes.

8.2 Ownership of Study Data. BMS shall own the Study Data to the extent that it relates exclusively to the BMS Study Drug ("BMS Study Data"), and the Recipient shall own the Study Data to the extent that it relates exclusively to the Recipient Study Drug ("Recipient Study Data"). Both Parties shall jointly own any Study Data that does not relate exclusively to the Recipient Study Drug or the BMS Study Drug ("Combined Therapy Study Data"). Each Party shall, and does hereby, assign, and shall cause its Affiliates to so assign, to the other Party, without additional compensation, such right, title and interest in and to any Study Data as is necessary to fully effect the foregoing, and agrees to execute all instruments as may be reasonably necessary to effect same.

8.3 Use of Study Data.

(a) Use of a Party's Own Study Data. BMS may use and analyze the BMS Study Data for any purpose without obligation or accounting to the Recipient, who shall hold the BMS Study Data in confidence pursuant to this Agreement. The Recipient may use and analyze the Recipient Study Data for any purpose without obligation or accounting to BMS, who shall hold the Recipient Study Data in confidence pursuant to this Agreement.

(b) Use of Combined Therapy Study Data by BMS. BMS, []* and their respective Affiliates and (sub)licensees shall have the right to use and analyze the Combined Therapy Study Data (i) in connection with the independent development, commercialization or other exploitation of the BMS Study Drug (alone or in combination with other drugs and/or other pharmaceutical agents) and/or for inclusion in the safety database for the BMS Study Drug, in each case without the consent of, or any obligation to

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account to, the Recipient, and (ii) to conduct studies with Samples pursuant to Section 8.5. Subject to Section 8.5, the results of all such analyses or uses shall be owned by BMS, including any intellectual property arising out of same, unless the Parties shall have agreed otherwise in a writing separate from this Agreement. BMS, []*, and their respective Affiliates and (sub)licensees shall also be entitled to use the Combined Therapy Study Data during and following the Term to (1) make regulatory filings, meet regulatory requirements, and seek approvals for the BMS Study Drug, either alone or as part of the Combined Therapy, (2) evaluate the safety and efficacy of the Combined Therapy and the BMS Study Drug, (3) promote indications based on, and to disseminate, the Combined Therapy Study Data for the benefit of the BMS Study Drug, either alone or as part of the Combined Therapy, where permitted by and in accordance with Applicable Law; *provided that* nothing in the foregoing is intended or shall be construed as granting BMS any right or license, expressly or impliedly to make, have made, use, sell, offer for sale, or import the Recipient Study Drug; and (4) include in Patent Rights filings made in the course of the prosecution of BMS Independent Patent Rights that do not Cover both the composition of matter of the Recipient Study Drug, its manufacture or formulation, method of use and the BMS Study Drug. The Recipient grants BMS, []*, their respective Affiliates and (sub)licensees (of rights to the BMS Study Drug) a Right of Cross-Reference to the Recipient Regulatory Documentation Controlled by Recipient for the Recipient Study Drug and the Combined Therapy Clinical Trial Regulatory Documentation for the Recipient Study Drug or the Combined Therapy for the sole purpose of enabling BMS, []* and their Affiliates and sublicensees to exercise its rights under clause (1) of this Section 8.3(b), which right shall survive any expiration or termination of this Agreement.

Use of Combined Therapy Study Data by the Recipient. The Recipient and its Affiliates and licensees shall have the right to (c) use and analyze the Combined Therapy Study Data (i) in connection with the independent development, commercialization or other exploitation of the Recipient Study Drug (alone or in combination with other drugs and/or other pharmaceutical agents) and/or for inclusion in the safety database for the Recipient Study Drug, in each case without the consent of, or any obligation to account to, BMS and (ii) to conduct studies with Samples pursuant to Section 8.5. Subject to Section 8.5, the results of all such analyses or uses shall be owned by the Recipient, including any intellectual property arising out of same, unless the Parties shall have agreed otherwise in writing separate from this Agreement. The Recipient, its Affiliates and (sub)licensees shall be entitled to use the Combined Therapy Study Data during and following the Term to (1) make regulatory filings, meet regulatory requirements and seek approvals for the Recipient Study Drug, either alone or as part of the Combined Therapy, (2) evaluate the safety and efficacy of the Combined Therapy and the Recipient Study Drug, (3) promote indications based on, and to disseminate, the Combined Therapy Study Data for the benefit of the Recipient Study Drug, either alone or as part of the Combined Therapy, where permitted by and in accordance with Applicable Law; provided that nothing in the foregoing is intended or shall be construed as granting the Recipient any right or license, expressly or impliedly, to make, have made, use, sell, offer for sale, or import the BMS Study Drug; and (4) and include in Patent Rights filings made in the course of the prosecution of Recipient Independent Patent Rights that do not Cover both the composition of matter of the BMS Study Drug, its manufacture or formulation, method of use and the Recipient Study Drug. BMS grants the Recipient, its Affiliates and licensees of the Recipient Study Drug a Right of Cross-Reference to the relevant Regulatory Documentation Controlled by BMS for the BMS Study Drug for the sole purpose of enabling the Recipient, its Affiliates and (sub)licensees to exercise its rights under clause (1) of this Section 8.3(c) (for clarity, such Right of Cross-Reference shall not extend to any []*-controlled Regulatory Documentation) in all countries and territories of the world, which right shall survive any expiration or termination of this Agreement.

(d) **Biomarker/Dx Agent Development.** Each Party may use and disclose to a Third Party the Combined Therapy Study Data and its Compound's Study Data, under obligations of confidentiality consistent with this Agreement, to develop and commercialize a biomarker or diagnostic test for use with its Compound (including without limitation another combination therapy involving its Compound) and/or the Combined Therapy, and, unless otherwise mutually agreed by the Parties in writing,

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will own any intellectual property arising out of the work funded or conducted by it with or through such Third Party. Each Party shall grant, and hereby grants, to the other Party a worldwide, perpetual, irrevocable, fully paid-up, royalty-free non-exclusive license, with the right to grant and authorize sublicenses, under such intellectual property and data to develop and commercialize biomarkers and/or diagnostic tests for use with the Combined Therapy. The Parties will discuss in good faith any opportunities to jointly participate in the development of any such biomarker or diagnostic test for use with the Combined Therapy.

(e) No Other Uses. All other uses of Combined Therapy Study Data (by either Party), Recipient Study Data (by BMS) and BMS Study Data (by the Recipient) are limited solely to those permitted by this Agreement, and neither Party may use such Study Data for any other purpose without the consent of the other Party during and after the Term.

8.4 Access to Study Data. Subject to the provisions of Sections 8.1, each Party shall have access to all Combined Therapy Study Data, Recipient Study Data and BMS Study Data (including de-identified patient records). The relevant Party shall make such Study Data in its possession available to the other Party within a reasonable period, not to exceed []*, after such Study Data is available to or generated by the applicable Party.

8.5 Samples.

(a) Samples shall be jointly owned by the Parties (to the extent not owned by the patient and/or the clinical trial site). Any such Samples shall be collected in accordance with the Protocol and applicable ICFs. Except as set forth in the Protocol, neither Party shall be permitted to use such Samples for any purpose without the prior written consent of the other Party, which consent shall not be unreasonably withheld if such use is directed to the Combined Therapy and with the terms of such use to be set forth in a written agreement between the Parties setting forth the Samples to be used, and any appropriate terms/restrictions on such use. For clarity, Replimune shall have the right, without further consent of BMS, to use and study any such Samples as set forth in the Protocol, it being understood that if the Protocol does not reference specific assays to be utilized in the analysis of any such Samples and such analysis will be in the discretion of Replimune. Except for intellectual property pertaining solely to the []* (which shall be owned by BMS), any data and intellectual property relates solely to the Combined Therapy (or biomarkers solely for use with the Combined Therapy), shall be considered Combined Therapy Study Data, Combined Therapy Inventions and/or Combined Therapy Patent Rights, as the case may be. All Samples, including Samples for PK and ADA serum analysis will be stored for future use in the Recipient's sample repository, unless the Parties mutually agree that BMS would store such samples, *provided that*, if the Party holding the Samples determines that it no longer has a use for the Samples and the other Party determines that it does, then the Samples shall, subject to Applicable Law and the terms of the signed ICFs, be transferred to the other Party and may be used solely thereafter by the other Party. If neither Party has any further use for the Samples, then the remaining Samples will be destroyed pursuant to the respective Party's standard operating

procedures for sample retention and destruction, subject to the terms of and permission(s) granted in the informed consent forms signed by the subjects contributing the Samples in the Combined Therapy Clinical Trial.

(b) If required by a Regulatory Authority or necessary as part of the Protocol or related bioanalysis plan, BMS will arrange for the Recipient to use BMS's preferred Third Party vendor(s), at the Recipient's expense, for bioanalytical work of Samples from Combined Therapy Clinical Trial subjects on the BMS Study Drug. Such vendor(s) will provide the results of their bioanalytical work of such Samples to the Recipient and BMS, which results will be included in the final clinical study report, along with the bioanalytical work of the Recipient Study Drug and BMS Study Drug performed by or on behalf of the Recipient. For the avoidance of doubt, all bioanalytical results for the BMS Study Drug and

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the Recipient Study Drug are deemed Study Data. All data derived pursuant to the Protocol from such Samples is deemed Study Data.

ARTICLE 9

CONFIDENTIALITY

9.1 Nondisclosure of Confidential Information.

(a) Prior to the Effective Date, the Recipient and BMS entered into a certain Confidentiality Agreement dated March 27, 2017 (the "*CDA*"). As it relates to disclosures involving the BMS Study Drug, the Recipient Study Drug or the conduct of the Combined Therapy Clinical Trial only, the CDA is hereby terminated and replaced by the terms of this Agreement. Any Confidential Information relating thereto previously disclosed by the Parties pursuant to the CDA shall now be Confidential Information for purposes of this Agreement and the Parties shall treat it as such in accordance with the terms hereof. All written, visual, oral and electronic data, information, know-how or other proprietary information or materials, both technical and non-technical, disclosed by one Party to the other Party pursuant to this Agreement, and disclosed in the manner specified herein, that (a) if in tangible form, is labeled in writing as "proprietary" or "confidential" (or similar reference), or (b) if in oral or visual form, is identified as proprietary or confidential or for internal use only at the time of disclosure or within thirty (30) calendar days thereafter shall be "*Confidential Information*" of the disclosing Party, and all Study Data and Inventions shall be the Confidential Information of the Party (or Parties) owning such Study Data or Invention (as provided in Section 8.2 with regard to Study Data and Section 6.1 with regard to Inventions). For purposes of this Agreement, regardless of which Party discloses such Confidential Information of the Recipient Technology and Recipient Regulatory Documentation shall be Confidential Information of the Recipient and BMS shall be the receiving Party, and (ii) all BMS Study Inventions, BMS Technology, and BMS Regulatory Documentation shall be Confidential Information of the Recipient shall be the receiving Party.

(b) The Parties agree that the terms of this Agreement shall be treated as Confidential Information of both Parties, and thus may be disclosed only as permitted by Section 9.3. Except as required by Applicable Law, each Party agrees not to issue any press release or public statement disclosing information relating to this Agreement or the transactions contemplated hereby or the terms hereof without the prior written consent of the other Party, except as permitted by Section 9.3 and 9.6(b).

(c) Except to the extent expressly authorized in this Section 9.1 and Sections 9.2, 9.3 and 9.6 below, or as otherwise agreed in writing by the Parties, each Party agrees that, for the Term and for a period of []* thereafter, it shall (A) keep confidential and shall not publish or otherwise disclose and shall not use for any purpose other than as expressly provided for in this Agreement any Confidential Information of the other Party (including information relating to this Agreement or the transactions contemplated hereby or the terms hereof), (B) treat the other Party's Confidential Information with the same degree of care the receiving Party uses for its own confidential information but in no event with less than a reasonable degree of care; and (C) reproduce the disclosing Party's Confidential Information solely to the extent necessary or reasonably useful to accomplish the receiving Party's obligations under this Agreement or exercise the receiving Party's rights to use and disclose such Confidential Information as expressly provided for in this Agreement, with all such reproductions being considered the disclosing Party's Confidential Information, *provided that*, with respect to BMS Confidential Information from []*, the obligations of confidentiality and nonuse shall continue until BMS has obtained []* written consent that the same may be freely used. Notwithstanding anything to the contrary in this Section 9.1, and subject to Section 8.3, the receiving Party is obligations under this Agreement or exercising Party's obligations under this Agreement or the transaction from []*, the obligations of permitted (sub)licensees solely on a need-to-know basis for the purpose of fulfilling the receiving Party's obligations under this Agreement or exercising the receiving Party's obligations under this Agreement or exercising the receiving Party's obligations under this Agreement or exercising the receiving Party's obligations under this Agreement or exercising the receiving Party's obligations under this Agreement

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Party's rights to use and disclose such Confidential Information as expressly provided for in this Agreement; *provided, however, that* (1) any such employees, consultants, agents or permitted (sub)licensees are bound by obligations of confidentiality and non-use at least as restrictive as those set forth in this Agreement, and (2) the receiving Party remains liable for the compliance of such employees, consultants, agents or permitted (sub)licensees with such obligations. Each receiving Party acknowledges that in connection with its and its representatives examination of the Confidential Information of the disclosing Party, the receiving Party and its representatives may have access to material, non-public information, and that the receiving Party is aware, and will advise its representatives who are informed as to the matters that are the subject of this Agreement, that State and Federal laws, including United States securities laws, may impose restrictions on the dissemination of such information and trading in securities when in possession of such information. Each receiving Party agrees that it will not, and will advise its representatives who are informed as to the matters that are the subject of the matters that are the subject of this Agreement to not, purchase or sell any security of the disclosing Party on the basis of the Confidential Information to the extent such Confidential Information constitute material nonpublic information about the disclosing Party or such security.

(d) Combined Therapy Study Data shall be treated as Confidential Information of each Party and shall not be disclosed to Third Parties except to the extent it falls within the exceptions set forth in Section 9.2 below, is authorized under this Section 9.1 or Section 9.3, is required to be filed with a Regulatory Authority or included in a product's label or package insert, is reasonably necessary to be disclosed in order for a Party to exercise its rights under Section 8.3(b) or 8.3(c) or it is disclosed pursuant to Section 9.5.

9.2 Exceptions. The obligations in Section 9.1 shall not apply with respect to any portion of Confidential Information that the receiving Party can demonstrate by contemporaneous tangible records or other competent proof:

(a) was already known to the receiving Party (or its Affiliates), other than under an obligation of confidentiality, either (i) at the time of disclosure by the disclosing Party, or (ii) if applicable, at the time that it was generated hereunder, whichever ((i) or (ii)) is earlier;

(b) was generally available to the public or otherwise part of the public domain either (i) at the time of its disclosure to the receiving Party, or (ii) if applicable, at the time that it was generated hereunder, whichever ((i) or (ii)) is earlier;

(c) became generally available to the public or otherwise part of the public domain after its disclosure and other than through any act or omission of the receiving Party in breach of this Agreement;

(d) was disclosed to the receiving Party (or its Affiliates), other than under an obligation of confidentiality, by a Third Party who had no obligation to the Party owning or Controlling the information not to disclose such information to others; or

(e) was independently discovered or developed by the receiving Party (or its Affiliates) without the use of, or reference to, the Confidential Information belonging to the disclosing Party.

9.3 Authorized Disclosure. Notwithstanding any other provision of this Agreement, each Party may disclose Confidential Information belonging to the other Party to the extent such disclosure is reasonably necessary in the following instances:

- (a) filing or prosecuting Patent Rights pursuant to Section 6.1(c);
- (b) prosecuting or defending litigation;

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(c) complying with Applicable Law or the rules or regulations of any securities exchange on which such Party's stock is listed;

(d) disclosure, in connection with the performance of this Agreement, to Affiliates, permitted (sub)licensees, contractors, IRBs, CROs, academic institutions, consultants, agents, investigators, and employees and contractors engaged by study sites and investigators involved with the Combined Therapy Clinical Trial, each of whom prior to disclosure must be bound by terms of confidentiality and non-use at least as protective of Confidential Information as those set forth in this Article 9;

(e) disclosure of the Combined Therapy Study Data, Combined Therapy Inventions and Combined Therapy Patent Rights to Regulatory Authorities in connection with the development and obtaining of regulatory approval of the Combined Therapy, the Recipient Study Drug or the BMS Study Drug;

(f) disclosure of relevant safety information contained within the Combined Therapy Study Data to investigators, IRBs and/or ethics committees and Regulatory Authorities that are involved in other clinical trials of the Recipient Study Drug with respect to the Recipient, and the BMS Study Drug with respect to BMS, and, in the event of a Material Safety Issue, to Third Parties that are collaborating with the Recipient or BMS, respectively in the conduct of such other clinical trials of the Recipient Study Drug or the BMS Study Drug, in each case solely to the extent necessary for the conduct of such clinical trials and/or to comply with Applicable Law and regulatory requirements; and

(g) subject to a []* advance written notice to BMS, in communications with []* under confidentiality provisions as least as protective of Confidential Information as those of this Agreement; *provided* that with respect to []* such disclosure shall be limited to the terms and conditions of this Agreement and the Combined Therapy Study Data.

Notwithstanding the foregoing, if a Party is required or otherwise intends to make a disclosure of any other Party's Confidential Information pursuant to Section 9.3(b) and/or Section 9.3(c), it shall give advance notice to such other Party of such impending disclosure and endeavor in good faith to secure confidential treatment of such Confidential Information and/or reasonably assist the Party that owns such Confidential Information in seeking a protective order or other confidential treatment.

9.4 Disclosure to []*. Notwithstanding any other provision of this Agreement, BMS shall be entitled to disclose to []* (a) the existence (but not the terms) of this Agreement, the Combined Therapy Clinical Trial and the Protocol, and (b) any other Recipient Confidential Information necessary for BMS to fulfill its obligations to []* under the []*-BMS Agreements; *provided that* []* is under confidentiality obligations at least as restrictive as set forth herein. BMS shall be free to disclose to []* and permit []* to use the BMS Study Data and the Combined Therapy Study Data as BMS may determine (so long as such use is consistent with BMS's permitted uses under Section 8.3(b)).

9.5 Press Releases and Publications.

(a) The Parties shall jointly agree to the content and timing of all public communications with respect to this Agreement, press releases, Q&As, and the content of, and wording for, any listing of the Combined Therapy Clinical Trial required to be listed on a public database or other public registry such as www.clinicaltrials.gov). For clarity, if either Party terminates this Agreement pursuant to Section 12.4, the Parties shall mutually agree upon any external communication related to such termination, which shall not include the rationale for such termination unless (and to the extent) mutually agreed by the Parties. Notwithstanding the foregoing in this Section 9.5(a), either Party shall be permitted to publicly disclose information that such Party determines in good faith is necessary to be disclosed to comply with

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Applicable Law or the rules or regulations of any securities exchange on which such Party's stock may be listed, or pursuant to an order of a court or governmental entity.

The Recipient and BMS agree to collaborate to publicly disclose, publish or present (i) top-line results from the Combined (b) Therapy Clinical Trial, limited if possible to avoid jeopardizing the future publication of the Study Data at a scientific conference or in a scientific journal, solely for the purpose of disclosing, as soon as reasonably practicable, the safety or efficacy results and conclusions that are material to either Party under applicable securities laws, and (ii) the conclusions and outcomes (the "Results") of the Combined Therapy Clinical Trial at a scientific conference as soon as reasonably practicable following the database lock date for such Combined Therapy Clinical Trial, subject in the case of (ii) to the following terms and conditions. The Party proposing to disclose, publish or present the Results shall deliver to the other Party a copy of the proposed disclosure, publication or presentation at least []* before submission to a Third Party. The reviewing Party shall determine whether any of its Confidential Information that may be contained in such disclosure, publication or presentation should be modified or deleted, whether to file a patent application on any Recipient Study Invention (solely with respect to the Recipient) or BMS Study Invention (solely with respect to BMS) or Combined Therapy Invention disclosed therein. The disclosure, publication or presentation shall be delayed for an additional []* (i.e., a total of []* from the initial proposal) if the reviewing Party reasonably requests such extension to allow time for the preparation and filing of relevant patent applications consistent with the terms of this Agreement. If the reviewing Party reasonably requests modifications to the disclosure, publication or presentation to prevent the disclosure of Confidential Information of the reviewing Party (other than the Results or Study Data), the publishing Party shall edit such publication to prevent the disclosure of such information prior to submission of the disclosure, publication or presentation. In the event of a disagreement as to content, timing and/or venue or forum for any disclosure, publication or presentation of the Results, such dispute (a "Publication Dispute") shall be referred to the Executive Officers (or their respective designees); provided that, in the absence of agreement after such good faith discussions, and upon expiration of the additional []* -period, (A) academic collaborators or clinical trial sites engaged by the Recipient in connection with the performance of the Combined Therapy Clinical Trial may publish Combined Therapy Study Data obtained by such academic collaborator or clinical trial site solely to the extent that such ability to publish such Combined Therapy Study Data is set forth in an agreement between the Recipient and such academic collaborator or clinical trial site relating to the conduct of Combined Therapy Clinical Trial and (B) the publishing Party may proceed with the disclosure, publication or presentation provided that such disclosure, publication or presentation is consistent with its internal publication guidelines and customary industry practices for the publication of similar data and does not disclose the Confidential Information of the other Party (other than the Results or Study Data). Authorship of any publication shall be determined based on the accepted standards used in peer-reviewed academic journals at the time of the proposed disclosure, publication or presentation. The Parties agree that they shall make reasonable efforts to prevent publication of a press release that could jeopardize the future publication of Study Data at a scientific conference or in a scientific journal but in no way will this or any other provision of this Agreement supersede the requirements of any Applicable Law or the rules or regulations of any securities exchange or listing entity on which a Party's stock is listed (including any such rule or regulation that may require a Party to make public disclosures about interim results of the Combined Therapy Clinical Trial). Notwithstanding the foregoing, nothing herein shall prevent or restrict []* from making any disclosures of published Study Data disclosed to it by BMS pursuant to Section 9.4 or of the existence of this Agreement, in each case in order for []* to comply with requirements of Applicable Law, the rules or regulations of any securities exchange or listing entity on which its stock may be traded or pursuant to an order of a court or governmental entity to publicly disclose the existence of the Agreement and the Study Data, provided that if any such disclosure is made

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by []* it will only disclose the minimum amount of information necessary to achieve compliance and will provide the Recipient with reasonable advance notice of such disclosure.

(c) The Recipient agrees to include in all permitted press releases, presentations and publications it makes related to the Combined Therapy Clinical Trial specific mention, if applicable, of the BMS Study Drug and the support and involvement of BMS. BMS agrees to include in all permitted press releases, presentations and publications it makes related to the Combined Therapy Clinical Trial specific mention, if applicable, of the Recipient Study Drug and the support and involvement of the Recipient Study Drug and the support and involvement of the Recipient.

9.6 Compliance with Sunshine Laws.

(a) For purposes of compliance with reporting obligations under Sunshine Laws, as between the Parties, the Recipient/the Recipient represents that it is not, as of the Effective Date, subject to reporting obligations under the Sunshine Laws. Therefore, as between the Parties, BMS will report payments or other transfers of value ("*POTV*") made by the Recipient or the CRO related to the conduct of the Combined Therapy Clinical Trial and any applicable associated contractor engagements as required under the Sunshine Laws for the Combined Therapy Clinical Trial. BMS shall request delayed publication for any reported POTV for studies sponsored by the Recipient as permitted under the Sunshine Laws and if consistent with BMS's normal business practices. In the event that the Recipient becomes responsible for reporting POTV for studies sponsored by it in a given country during the Term, the Recipient shall provide written notification to BMS and the Parties will meet to confer to discuss how they wish to handle reporting thereafter. Interpretation of the Sunshine Laws for purposes of reporting any POTV by a Party shall be in such Party's sole discretion so long as the interpretation complies with Applicable Law.

(b) The Recipient (i) will provide (to the extent in the possession of the Recipient), or will utilize Commercially Reasonable Efforts to obligate and ensure that each CRO and other applicable Third Party contractors for the Combined Therapy Clinical Trial provides, BMS with any information requested by BMS as BMS may reasonably determine is necessary for BMS to comply with its reporting obligations under Sunshine Laws (with such amounts paid to, or at the direction of, healthcare providers, teaching hospitals and/or any other persons for whom POTVs must be reported under Sunshine Laws to be reported to BMS within a reasonable time period specified by BMS) and (ii) will reasonably cooperate with, and will utilize Commercially Reasonable Efforts to obligate and ensure that each CRO and other applicable Third Party contractors for the Combined Therapy Clinical Trial reasonably cooperates with, BMS in connection with its compliance with such Sunshine Laws. The form in which the Recipient provides any such information shall be mutually agreed but sufficient to enable BMS to comply with its reporting obligations and BMS may disclose any information that it believes is necessary to comply with Sunshine Laws. Without limiting the foregoing, BMS shall have the right to allocate POTVs in connection with this Agreement in any required reporting under Sunshine Laws in accordance with its normal business practices. These obligations shall survive the expiration and termination of this Agreement to the extent necessary for BMS to comply with Sunshine Laws. The Recipient shall not be required to provide any information to BMS that is subject to disclosure pursuant to the Recipient's own obligations under the Sunshine Laws.

(c) For purposes of this Section 9.7, "*Sunshine Laws*" shall mean Applicable Laws requiring collection, reporting and disclosure of POTVs to certain healthcare providers, entities and individuals. These Applicable Laws may include relevant provisions of the Patient Protection and Affordable Health Care Act of 2010 and implementing regulations thereunder.

9.7 Destruction of Confidential Information. Upon expiration or termination of the Agreement, the receiving Party shall, upon request by the other Party, immediately destroy or return all of the other Party's Confidential Information relating solely to its Compound as monotherapy (but not to the Combined Therapy or the Combined Therapy Study Data) in its possession; *provided, however, that* the receiving Party shall be entitled to retain one (1) copy of Confidential Information solely for record-keeping

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purposes and shall not be required to destroy any Confidential Information required, or reasonably necessary, to be retained for any clinical trial activities that continue after expiration or termination, or off-site computer files created during automatic system back up which are subsequently stored securely by the receiving Party.

9.8 Nonsolicitation of Employees. Each Party agrees that, during the []* thereafter, neither it nor any of its Affiliates shall recruit, solicit or induce any employee of the other Party directly involved in the development or other activities conducted by the other Party under this Agreement to terminate his or her employment with such other Party and become employed by or consult for such other Party, whether or not such employee is a full-time employee of such other Party, and whether or not such employment is pursuant to a written agreement or is at-will. For purposes of the foregoing, "recruit", "solicit" or "induce" shall not be deemed to mean (a) circumstances where an employee of one Party initiates contact with the other Party or any of its Affiliates with regard to possible employment, or (b) general solicitations of employment not specifically targeted at employees of a Party or any of its Affiliates, including responses to general advertisements.

ARTICLE 10

REPRESENTATIONS AND WARRANTIES

10.1 Authority and Binding Agreement. Each Party represents and warrants to the other Party that (a) it has the corporate power and authority and the legal right to enter into this Agreement and perform its obligations hereunder, (b) it has taken all necessary corporate action on its part required to authorize the execution and delivery of the Agreement and the performance of its obligations hereunder, and (c) the Agreement has been duly executed and delivered on behalf of such Party and constitutes a legal, valid and binding obligation of such Party that is enforceable against it in accordance with its terms subject to bankruptcy, insolvency, reorganization, arrangement, winding-up, moratorium, and similar laws of general application affecting the enforcement of creditors' rights generally, and subject to general equitable principles, including the fact that the availability of equitable remedies, such as injunctive relief or specific performance, is in the discretion of the court.

10.2 No Conflicts. Each Party represents and warrants to the other Party that, to the best of its knowledge, it has not entered as of the Effective Date, and shall not enter, into any agreement with any Third Party that is in conflict with the rights granted to the other Party under this Agreement, and has not taken any action that would in any way prevent it from granting the rights granted to the other Party under this Agreement, or that would otherwise materially conflict with or adversely affect the rights granted to the other Party under this Agreement.

10.3 Litigation. Each Party represents and warrants to the other Party, to the best of its knowledge as of the Effective Date, it is not aware of any pending or threatened litigation (and has not received any communication) that alleges that its activities related to this Agreement have violated, or that by conducting the activities as contemplated in this Agreement it would violate, any of the intellectual property rights of any other Person (after giving effect to the license grants in this Agreement).

10.4 No Adverse Proceedings. Each Party represents and warrants to the other Party that, except as otherwise notified to the other Party, as of the Effective Date, there is not pending or, to the knowledge of such Party, threatened, against such Party, any claim, suit, action or governmental proceeding that would, if adversely determined, materially impair the ability of such Party to perform its obligations under this Agreement.

10.5 Consents. Each Party represents and warrants to the other Party that, to the best of its knowledge, all necessary consents, approvals and authorizations of all regulatory and governmental authorities and other Persons (a) required as of the Effective Date to be obtained by such Party in connection

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with the execution and delivery of this Agreement have been obtained (or will have been obtained prior to such execution and delivery) and (b) required to be obtained by such Party in connection with the performance of its obligations under this Agreement have been obtained or will be obtained prior to such performance.

10.6 No Debarment. Each Party hereby certifies to the other that it has not used, and will not use the services of any person disqualified, debarred, banned, subject to debarment or convicted of a crime for which a person could be debarred by the FDA under 21 U.S.C. 335a, as amended (or subject to a similar sanction of any other Regulatory Authority), in any capacity in connection with any of the services or work provided under the Combined Therapy Clinical Trial and that this certification may be relied upon in any applications to the FDA or any other Regulatory Authority. It is understood and agreed that this certification imposes a continuing obligation upon each Party to notify the other promptly of any change in the truth of this certification. Upon request by a Party, the other Party agrees to provide a list of persons used to perform the services or work provided under any activities conducted for or on behalf of such Party or any of its Affiliates pursuant to this Agreement who, within the five (5) years preceding the Effective Date, or subsequent to the Effective Date, were or are convicted of one of the criminal offenses required by 21 U.S.C. 335a, as amended, to be listed in any application for approval of an abbreviated application for drug approval.

10.7 Compliance with Applicable Law. Each Party represents and warrants to the other Party that it shall comply with all Applicable Law of the country or other jurisdiction, or any court or agency thereof, applicable to the performance of its activities hereunder or any obligation or transaction hereunder, including those pertaining to the production and handling of drug products, such as those set forth by the Regulatory Authorities, as applicable, and the applicable terms of this Agreement in the performance of its obligations hereunder.

10.8 Affiliates. Each Party represents and warrants to the other Party that, to the extent the intellectual property, Regulatory Documentation or Technology licensed by it hereunder are Controlled by its Affiliates or a Third Party, it has the right to use, and has the right to grant (sub)licenses to the other Party to use, such intellectual property, Regulatory Documentation or Technology in accordance with the terms of this Agreement.

10.9 Ethical Business Practices. Each Party represents and warrants to the other Party that neither it nor its Affiliates will make any payment, either directly or indirectly, of money or other assets, including the compensation such Party derives from this Agreement (collectively a "*Payment*"), to government or political party officials, officials of International Public Organizations, candidates for public office, or representatives of other businesses or persons acting on behalf of any of the foregoing (collectively "*Officials*") where such Payment would constitute violation of any law, including the Foreign Corrupt Practices Act of 1977, 15 U.S.C. §§ 78dd-1, et seq. In addition, regardless of legality, neither it nor its Affiliates will make any Payment either directly or indirectly to Officials if such Payment is for the purpose of improperly influencing decisions or actions with respect to the subject matter of this Agreement. All activities will be conducted in compliance with the U.S. False Claims Act and the U.S. Anti-Kickback Statute.

10.10 Accounting. Each Party represents and warrants to the other Party that all transactions under the Agreement shall be properly and accurately recorded in all material respects on its books and records and that each document upon which entries in such books and records are based is complete and accurate in all material respects.

10.11 Single Agent Compound Safety Issues. Each Party represents and warrants that, to the best of its knowledge as of the Effective Date, it is not aware of any material safety or toxicity issues with respect to its Single Agent Compound that are not reflected in the investigator's brochure for its Single Agent Compound existing as of the Effective Date.

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10.12 Compliance with Licensor Agreements. Each Party will use, and will cause its Affiliates to use, Commercially Reasonable Efforts to comply with its obligations under any agreements entered into by it or its Affiliates with a Third Party under which it is licensed any intellectual property rights or confidential information relating to a Compound (and not to voluntarily terminate same) to the extent necessary for the Combined Therapy Clinical Trial to be conducted and completed in accordance with the terms of this Agreement and for the other Party to receive the rights and benefits provided to it under this Agreement.

10.13 DISCLAIMER OF WARRANTY. THE EXPRESS REPRESENTATIONS AND WARRANTIES STATED IN THIS ARTICLE 10 ARE IN LIEU OF, AND THE PARTIES DO HEREBY DISCLAIM, ALL OTHER REPRESENTATIONS AND WARRANTIES, EXPRESS, IMPLIED OR STATUTORY, INCLUDING WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE OR USE, AND NON-INFRINGEMENT OF THIRD PARTY INTELLECTUAL PROPERTY RIGHTS.

ARTICLE 11

INDEMNIFICATION

11.1 BMS Indemnification. BMS hereby agrees to defend, hold harmless and indemnify (collectively, "*Indemnify*") the Recipient, its Affiliates, and its and their agents, directors, officers, employees and subcontractors (the "*Recipient Indemnitees*") from and against any and all liabilities, expenses and/or losses, including reasonable legal expenses and attorneys' fees (collectively "*Losses*") resulting from Third Party suits, claims, actions and demands (each, a "*Third Party Claim*") to the extent that they arise or result from (a) the negligence or intentional misconduct of any BMS Indemnitee or any (sub)licensee of BMS conducting activities on behalf of BMS under this Agreement, (b) any breach by BMS of any provision of this Agreement, (c) any injury (other than resulting from known adverse effects) to a subject in the Combined Therapy Clinical Trial to the extent caused by the BMS Study Drug, or (d) the use by BMS, its Affiliates, contractors or (sub)licensees of Combined Therapy Study Data, BMS Study Inventions, BMS Study Patent Rights, Combined Therapy Inventions and Combined Therapy Patent Rights (other than with respect to Third Party Claims that are covered under Section 6.4); but excluding, in each case ((a) through (d)), any such Losses to the extent arising or resulting from a cause or event for which the Recipient is obligated to Indemnify the BMS Indemnitees pursuant to Section 11.2.

11.2 Recipient Indemnification. The Recipient hereby agrees to Indemnify BMS, its Affiliates, and its and their agents, directors, officers, employees and subcontractors (the "*BMS Indemnitees*") from and against any and all Losses resulting from Third Party Claims to the extent that they arise or result from (a) the negligence or intentional misconduct of any Recipient Indemnitee or any (sub)licensee of the Recipient conducting activities on behalf of the Recipient under this Agreement, (b) any breach by the Recipient of any provision of this Agreement, (c) any injury to a subject in the Combined Therapy Clinical Trial not caused by the BMS Study Drug, or (d) the use by the Recipient, its Affiliates, contractors or (sub)licensees of Combined Therapy Study Data, Recipient Study Data, Recipient Study Inventions, Recipient Study Patent Rights, Combined Therapy Inventions and Combined Therapy Patent Rights (other than with respect to Third Party Claims that are covered under Section 6.4); but excluding, in each case ((a) through (d)), any such Losses to the extent arising or resulting from a cause or event for which BMS is obligated to Indemnify the Recipient Indemnitees pursuant to Section 11.1.

11.3 Indemnification Procedure. Each Party's agreement to Indemnify the other Party is conditioned on the performance of the following by the Party seeking indemnification: (a) providing written notice to the Indemnifying Party of any Loss and/or Third Party Claim of the types set forth in Section 11.1 and 11.2 promptly, and in any event within sixty (60) calendar days, after the Party seeking indemnification has knowledge of such Loss and/or Third Party Claim; *provided that*, any delay in complying with the

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requirements of this clause (a) will only limit the Indemnifying Party's obligation to the extent of the prejudice caused to the Indemnifying Party by such delay, (b) permitting the Indemnifying Party to assume full responsibility to investigate, prepare for and defend against any such Loss and/or Third Party Claim, (c) providing reasonable assistance to the Indemnifying Party, at the Indemnifying Party's expense, in the investigation of, preparation for and defense of any Loss and/or Third Party Claim, and (d) not compromising or settling such Loss and/or Third Party Claim without the Indemnifying Party's written consent, such consent not to be unreasonably withheld or delayed.

11.4 Separate Defense of Claims. In the event that the Parties cannot agree as to the application of Sections 11.1 and/or 11.2 to any particular Loss, the Parties may conduct separate defenses of such Loss. Each Party further reserves the right to claim indemnity from the other in accordance with Sections 11.1 and/or 11.2 upon resolution of the underlying claim, notwithstanding the provisions of Section 11.3(b).

11.5 Insurance. Each Party shall maintain commercially reasonable levels of insurance or other adequate and commercially reasonable forms of protection or self-insurance to satisfy its indemnification obligations under this Agreement. Each Party shall provide the other Party with written notice at least thirty (30) calendar days prior to the cancellation, non-renewal or material change in such insurance or self-insurance which would materially adversely affect the rights of the other Party hereunder. The maintenance of any insurance shall not constitute any limit or restriction on damages available to a Party under this Agreement.

11.6 LIMITATION OF LIABILITY. NEITHER PARTY SHALL BE LIABLE TO THE OTHER PARTY FOR INDIRECT, INCIDENTAL, CONSEQUENTIAL OR SPECIAL DAMAGES, INCLUDING LOST PROFITS, ARISING FROM OR RELATING TO THIS AGREEMENT AND/OR SUCH PARTY'S PERFORMANCE HEREUNDER, REGARDLESS OF ANY NOTICE OF THE POSSIBILITY OF SUCH DAMAGES AND REGARDLESS OF THE CAUSE OF ACTION (WHETHER IN CONTRACT, TORT, BREACH OF WARRANTY OR OTHERWISE). NOTHING IN THIS SECTION 11.6 IS INTENDED TO LIMIT OR RESTRICT THE INDEMNIFICATION RIGHTS OR OBLIGATIONS OF A PARTY UNDER SECTIONS 11.1 OR 11.2 IN RELATION TO, OR DAMAGES AVAILABLE FOR, BREACHES OF CONFIDENTIALITY OBLIGATIONS IN ARTICLE 9 OR FOR A PARTY'S GROSS NEGLIGENCE OR WILLFUL MISCONDUCT.

ARTICLE 12

TERM AND TERMINATION

12.1 Term. This Agreement shall be effective as of the Effective Date and, unless earlier terminated pursuant to this Section 12.1, Sections 12.2, 12.3 or 12.4 or any other termination right expressly stated in this Agreement, shall continue in effect until completion of the Combined Therapy Clinical Trial by all centers participating in the Combined Therapy Clinical Trial, delivery of all Study Data, including all completed case report forms, all final analyses and all final clinical study reports contemplated by the Combined Therapy Clinical Trial to both Parties, and the completion of any statistical analyses and bioanalyses contemplated by the Protocol or otherwise agreed to by the Parties to be conducted under this Agreement (the "*Term*"). Notwithstanding the foregoing, either Party shall have the right to immediately terminate this Agreement if the Parties do not agree to a draft Protocol pursuant to Section 2.1(a) within []* after the Effective Date on written notice to the other Party within []* after the end of such []* period; provided that Recipient shall reimburse BMS its cost of Manufacture and supply (including shipping, taxes and duty, if applicable) for any BMS Study Drug supplied to Recipient for the Combined Therapy Clinical Trial prior to such termination.

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12.2 Termination for Material Breach.

(a) Notice and Cure Period. If a Party (the "*Breaching Party*") is in material breach of its obligations under this Agreement, the other Party (the "*Non-Breaching Party*") shall have the right to give the Breaching Party notice specifying the nature of such material breach. The Breaching Party shall have a period of []* after receipt of such notice to cure such material breach (the "*Cure Period*") in a manner reasonably acceptable to the Non-Breaching Party. For the avoidance of doubt, this provision is not intended to restrict in any way either Party's right to notify the other Party of any other breach or to demand the cure of any other breach.

(b) Termination Right. The Non-Breaching Party shall have the right to terminate this Agreement, upon written notice, in the event that the Breaching Party has not cured such material breach within the Cure Period, *provided*, *however*, *that* if such breach is capable of cure but cannot be cured within the Cure Period, and the Breaching Party commences actions to cure such material breach within the Cure Period and thereafter diligently continue such actions, the Breaching Party shall have an additional []* to cure such breach. If a Party contests such termination pursuant to the dispute resolution procedures under Section 13.3, such termination shall not be effective until a conclusion of the dispute resolution procedures in Section 13.3, as applicable, resulting in a determination that there has been a material breach that was not cured within the Cure Period (which Cure Period shall be tolled for the period from notice of such dispute until resolution of such dispute pursuant to Section 13.3 or abandonment of such dispute by the disputing Party).

12.3 Termination for Bankruptcy. Either Party may terminate this Agreement if, at any time, the other Party shall file in any court or agency pursuant to any statute or regulation of any state, country or jurisdiction, a petition in bankruptcy or insolvency or for reorganization or for an arrangement or for the appointment of a receiver or trustee of such other Party or of such other Party's assets, or if the other Party proposes a written agreement of composition or extension of its debts, or if the other Party shall be served with an involuntary petition against it, filed in any insolvency proceeding, and such petition shall not be dismissed or stayed within []* after the filing thereof, or if the other Party will propose or be a party to any dissolution or liquidation, or if the other Party shall make an assignment for the benefit of its creditors.

12.4 Termination due to Material Safety Issue; Clinical Hold.

(a) Either Party shall have the right to terminate this Agreement immediately (after meeting and discussing with the other Party in good faith as described in the following sentence) upon written notice if it deems it necessary to protect the safety, health or welfare of subjects enrolled in the Combined Therapy Clinical Trial due to the existence of a Material Safety Issue. In the event of a termination due to a Material Safety Issue, prior to the terminating Party providing written notice, each Party's safety committee shall, to the extent practicable, meet and discuss in good faith the safety concerns raised by the terminating Party and consider in good faith the input, questions and advice of the non-terminating Party, but should any dispute arise in such

discussion, the dispute resolution processes set forth in Section 13.3 shall not apply to such dispute and the terminating Party shall have the right to issue such notice and such termination shall take effect without the Parties first following the procedures set forth in Section 13.3.

(b) If a Clinical Hold with respect to either the BMS Study Drug or the Recipient Study Drug should arise at any time after the Effective Date, the Parties will meet and discuss the basis for the Clinical Hold, how long the Clinical Hold is expected to last, and how they might address the issue that caused the clinical hold. If, after []* of discussions following the Clinical Hold, either Party reasonably concludes that the issue adversely impacts the Combined Therapy Clinical Trial and is not solvable or that unacceptable and material additional costs/delays have been and/or will continue to be incurred in the conduct of the Combined Therapy Clinical Trial, then such Party may immediately terminate this Agreement.

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12.5 Effect of Termination. Upon expiration or termination of this Agreement, (a) the licenses granted to the Recipient to conduct the Combined Therapy Clinical Trial in Section 3.1 (and any sublicenses granted under Section 3.2) shall terminate, and (b) the Parties shall use reasonable efforts to wind down activities under this Agreement in a reasonable manner and avoid incurring any additional expenditures or non-cancellable obligations; *provided that*, in the case of termination pursuant to Section 12.4, the Recipient may continue to dose subjects enrolled in the Combined Therapy Clinical Trial through completion of the Protocol if dosing is required by the applicable Regulatory Authority(ies) and/or Applicable Law. Any such wind-down activities will include the return to BMS, or destruction, of all BMS Study Drug provided to the Recipient and not consumed in the Combined Therapy Clinical Trial, except in the event that the Recipient terminates this Agreement pursuant to Section 12.2 or 12.3, in which case the Recipient shall continue to have the right to use any BMS Study Drug provided to Recipient for the conduct of the Combined Therapy Clinical Trial.

12.6 Survival. The following Articles and Sections of this Agreement and all definitions relating thereto shall survive any expiration or termination of this Agreement for any reason: Section 2.1(b), Section 2.4, Section 4.5, Sections 5.1(e)-(h), Section 5.1(j), Section 5.1(k), Section 5.1(o), Article 6 ("Intellectual Property"), Article 7 ("Costs and Expenses), Article 8 ("Records and Study Data"), Article 9 ("Confidentiality"); Article 10 ("Representations and Warranties"), Article 11 ("Indemnification"), Section 12.5 ("Effect of Termination"), Section 12.6 ("Survival"), Section 13.1 ("Entire Agreement"), Section 13.2 ("Governing Law"), Section 13.3 ("Dispute Resolution"), Section 13.4 ("Injunctive Relief"), Section 13.6 ("Notices"), Section 13.7 ("No Waiver, Modifications"), Section 13.8 ("No Strict Construction"), Section 13.9 ("Independent Contractor"), Section 13.10 ("Assignment, Licenses"), Section 13.11 ("Headings"), Section 13.13 ("Severability"), Section 13.15 ("No Benefit to Third Parties"), and Section 13.16 ("Construction").

ARTICLE 13

MISCELLANEOUS

13.1 Entire Agreement. The Parties acknowledge that this Agreement shall govern all activities of the Parties with respect to the Combined Therapy Clinical Trial from the Effective Date forward. This Agreement, including the Exhibits hereto and together with the Supply and Quality Documentation, sets forth the complete, final and exclusive agreement between the Parties concerning the subject matter hereof and supersedes all prior agreements and understandings between the Parties with respect to such subject matter. There are no covenants, promises, agreements, warranties, representations, conditions or understandings, either oral or written, between the Parties with respect to such subject matter other than as are set forth in this Agreement. All Exhibits attached hereto are incorporated herein as part of this Agreement.

13.2 Governing Law. This Agreement shall be governed and construed in accordance with the internal laws of the State of Delaware, USA, excluding any choice of law rules that may direct the application of the laws of another jurisdiction.

13.3 Dispute Resolution.

(a) The Parties' Designated Clinical Contacts (for clinical and regulatory matters) and the Parties Designated Supply Contacts (for supply matters) shall attempt in good faith to resolve any dispute or concern that either Party may bring to the other Party's attention.

(b) In the event of any dispute, controversy or claim arising out of, relating to or in connection with any provision of this Agreement (each a "*Dispute*"), other than a Publication Dispute or a dispute as to whether a Material Safety Issue exists, that cannot be resolved by the applicable Designated

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Contacts of each Party after a period of []*, then upon the request of either Party by written notice, the Parties shall refer such Dispute to the Executive Officers. This Agreement shall remain in effect during the pendency of any such dispute. In the event that no resolution is made by the Executive Officers (or their designee) in good faith negotiations within []* after such referral to them, then:

(i) if such Dispute constitutes an Arbitration Matter, such Dispute shall be resolved through arbitration in accordance with the remainder of this Section 13.3; *provided*, *however*, *that* with respect to any such Arbitration Matter Dispute that relates to a matter described in Section 13.4, either Party shall have the right to seek an injunction or other equitable relief without waiting for the expiration of such []*-period;

- apply;
- (ii) if such Dispute constitutes a Publication Dispute, the specific dispute resolution processes contained in Section 9.6(b) will

(iii) if such Dispute regards the supply, quality or compliance with specifications of the Recipient Study Drug, the Recipient shall have the final say regarding such Dispute; *provided that* (A) the Recipient shall have no authority to amend, change or waive compliance with this Agreement, which matters may be approved only by the written consent of both Parties, (B) all determinations made by the Recipient shall be consistent with the terms of this Agreement;

(iv) if such Dispute regards the supply, quality or compliance with specifications of the BMS Study Drug, BMS shall have the final say regarding such Dispute; *provided that* (A) BMS shall have no authority to amend, change or waive compliance with this Agreement, which matters may be approved only by the written consent of both Parties, (B) all determinations made by BMS shall be consistent with the terms of this Agreement.

If a Dispute that constitutes an Arbitration Matter remains unresolved after escalation to the Executive Officers as described above, either Party may refer such matter to arbitration as described herein. Any arbitration of an Arbitration Matter under this Agreement shall be shall be conducted under the auspices of the American Arbitration Association by a panel of three (3) arbitrators pursuant to that organization's Commercial Arbitration Rules then in effect.

(c) The fees and expenses of the arbitrators shall be borne in equal shares by the Parties. Each Party shall bear the fees and expenses of its legal representation in the arbitration. The arbitral tribunal shall not reallocate either the fees and expenses of the arbitrators or of the Parties' legal representation. The arbitration shall be held in New York, New York, which shall be the seat of the arbitration. The language of the arbitration shall be English.

13.4 Injunctive Relief. Notwithstanding anything herein to the contrary, a Party may seek an injunction or other injunctive relief from any court of competent jurisdiction in order to prevent immediate and irreparable injury, loss or damage on a provisional basis. For the avoidance of doubt, if either Party (a) discloses Confidential Information of the other Party other than as permitted under Article 9, (b) uses (in the case of the Recipient) the BMS Study Drug or BMS Technology or (in the case of BMS) the Recipient Study Drug or Recipient Technology in any manner other than as expressly permitted under this Agreement or (c) otherwise is in material breach of this Agreement and such material breach could cause immediate harm to the value of the Recipient Study Drug (by the Recipient) or the BMS Study Drug (by BMS), the other Party shall have the right to seek an injunction or other equitable relief precluding the other Party from continuing its activities related to the Combined Therapy Clinical Trial without waiting for the conclusion of the dispute resolution procedures under Section 13.3.

13.5 Force Majeure. The Parties shall be excused from the performance of their obligations under this Agreement (other than the payment of monies owed to the other Party) to the extent that such

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performance is prevented by force majeure and the non-performing Party promptly provides notice of the prevention to the other Party. Such excuse shall be continued so long as the condition constituting force majeure continues and the nonperforming Party takes reasonable efforts to remove the condition. For purposes of this Agreement, force majeure shall mean acts of God, strikes or other concerted acts of workers, civil disturbances, fires, earthquakes, acts of terrorism, floods, explosions, riots, war, rebellion, sabotage or failure or default of public utilities or common carriers or similar conditions beyond the control of the Parties.

13.6 Notices. Any notice required or permitted to be given under this Agreement shall be in writing, shall specifically refer to this Agreement and shall be deemed to have been sufficiently given for all purposes if such notice is timely and is: (a) mailed by first class certified or registered mail, postage prepaid, return receipt requested, (b) sent by express delivery service, or (c) personally delivered. Unless otherwise specified in writing, the mailing addresses of the Parties shall be as described below.

For the Recipient:	Replimune Inc. 18 Commerce Way Wolburn, MA 10801 Attention: Rob Coffin, CEO
For BMS:	Bristol-Myers Squibb Company Route 206 and Province Line Road Princeton, NJ 08543-4000 Attention: VP, Business Development
With a copy to:	Bristol-Myers Squibb Company Route 206 and Province Line Road Princeton, NJ 08543-4000 Attention: VP & Assistant General Counsel, Licensing and Business Development

Any such communication shall be deemed to have been received when delivered. It is understood and agreed that this Section 13.6 is not intended to govern the day-to-day business communications necessary between the Parties in performing their duties, in due course, under the terms of this Agreement.

13.7 No Waiver; Modifications. It is agreed that no waiver by a Party hereto of any breach or default of any of the covenants or agreements herein set forth shall be deemed a waiver as to any subsequent and/or similar breach or default. No amendment, modification, release or discharge shall be binding upon the Parties unless in writing and duly executed by authorized representatives of both Parties.

13.8 No Strict Construction. This Agreement has been prepared jointly and shall not be strictly construed against either Party. No presumption as to construction of this Agreement shall apply against either Party with respect to any ambiguity in the wording of any provision(s) of this Agreement irrespective of which Party may be deemed to have authored the ambiguous provision(s).

13.9 Independent Contractor. The Parties are independent contractors of each other, and the relationship between the Parties shall not constitute a partnership, joint venture or agency. Neither Party shall be the agent of the other or have any authority to act for, or on behalf of, the other Party in any matter.

(a) Assignment. Neither Party may assign or transfer this Agreement or any rights or obligations hereunder without the prior written consent of the other Party, *except* that a Party may make such an assignment without the other Party's consent (i) to an Affiliate, (ii) to a Third Party that merges

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with, consolidates with or acquires substantially all of the assets or voting control of the assigning Party or (iii) to a Third Party that acquires all the rights of the assigning Party to the Recipient Study Drug, in the case of the Recipient, or the BMS Study Drug, in the case of BMS. If assigned or transferred to an Affiliate, the assigning/transferring Party shall remain jointly and severally responsible and liable with the assignee/transferee Affiliate for the assigned rights and/or obligations. If assigned to a Third Party, any permitted successor or assignee of rights and/or obligations hereunder shall, in a writing to the other Party, expressly assume performance of such rights and/or obligations. Any assignment or attempted assignment by any Party in violation of the terms of this Section 13.10(a) shall be null and void and of no legal effect.

(b) Licensees. If a Party grants a third party a license (other than a license solely to make a product for a Party and other than any license rights granted to []* for the []* Territory) to develop and commercialize its Single Agent Compound on a worldwide basis or in any geographic region and/or for all purposes or a limited field, (a "*Licensee*"), such Party will obtain the Licensee's agreement to abide by the terms of this Agreement as and to the extent necessary in order for its obligations hereunder to be fulfilled in the same manner as the licensing Party; and in such event the licensing Party may exercise its rights granted hereunder (including rights to use Study Data and practice Inventions) through the Licensee.

13.11 Headings. The captions to the several Sections and Articles hereof are not a part of this Agreement, but are included merely for convenience of reference only and shall not affect its meaning or interpretation.

13.12 Counterparts. This Agreement may be executed in two (2) or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one (1) and the same instrument. This Agreement may be executed by facsimile or electronic (e.g., pdf) signatures and such signatures shall be deemed to bind each Party hereto as if they were original signature.

13.13 Severability. If any provision of this Agreement is held to be illegal, invalid or unenforceable under any present or future law, and if the rights or obligations of a Party under this Agreement will not be materially and adversely affected thereby, (a) such provision shall be fully severable, (b) this Agreement shall be construed and enforced as if such illegal, invalid or unenforceable provision had never comprised a part hereof, (c) the remaining provisions of this Agreement shall remain in full force and effect and shall not be affected by the illegal, invalid or unenforceable provision or by its severance herefrom and (d) in lieu of such illegal, invalid or unenforceable provision, there shall be added automatically as a part of this Agreement a legal, valid and enforceable provision as similar in terms to such illegal, invalid or unenforceable provision as may be possible and reasonably acceptable to the Parties.

13.14 Further Assurance. Each Party shall duly execute and deliver, or cause to be duly executed and delivered, such further instruments and do and cause to be done such further acts and things, including the filing of such assignments, agreements, documents and instruments, as may be necessary or as the other Party may reasonably request in order to perfect any license, assignment or other transfer or any properties or rights under, or pursuant, to this Agreement.

13.15 No Benefit to Third Parties. The representations, warranties and agreements set forth in this Agreement are for the sole benefit of the Parties and their successors and permitted assigns, and they shall not be construed as conferring any rights on any other parties.

13.16 Construction.

(a) General. Except as otherwise explicitly specified to the contrary, (i) references to a Section, Article or Exhibit means a Section or Article of, or Exhibit to, this Agreement and all subsections thereof, unless another agreement is specified, (ii) references to a particular statute or regulation include all rules and regulations promulgated thereunder and any successor statute, rules or regulations then in effect, in each case including the then-current amendments thereto, (iii) words in the singular or plural

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form include the plural and singular form, respectively, (iv) the terms "including," "include(s)," "such as," and "for example" used in this Agreement mean including the generality of any description preceding such term and will be deemed to be followed by "without limitation", and (v) the words "hereof," "herein," "hereunder," "hereby" and derivative or similar words refer to this Agreement. No presumption as to construction of this Agreement shall apply against either Party with respect to any ambiguity in the wording of any provision(s) of this Agreement irrespective of which Party may be deemed to have authored the ambiguous provision(s).

(b) No Response. Except as expressly set forth in this Agreement, where a provision of this Agreement provides for a Party to respond within a designated period following written notice from the other Party, and if such Party fails to respond, then the failure to respond shall not be deemed to create or imply: (i) that the non-responding Party agrees or disagrees with the proposed action to be taken by the other Party, (ii) any amendment, change or waiver of the terms of this Agreement, or (iii) any consent that an action proposed to be taken may be taken if it conflicts with the terms of this Agreement and/or waiver of any rights it may have to seek remedies at law or in equity for breach of this Agreement as a result of the action taken.

[Signature page follows]

IN WITNESS WHEREOF, the Parties, intending to be legally bound hereby, have caused this Agreement to be executed by their duly authorized representatives as of the Effective Date.

Replimune Inc.		Bristol-Myers Squibb Company	
By:	/s/ Robert Coffin	By:	/s/ Fouad Namouni
Name:	Robert Coffin	Name:	Dr. Fouad Namouni, MD
Title:	CEO	Title:	Head of Oncology Development
Date:	21st February 2018	Date:	February 26, 2018
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APPENDIX A

DRAFT PROTOCOL SUMMARY

[]*

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REPLIMUNE GROUP, INC. REQUESTS THAT THE MARKED PORTIONS OF THIS EXHIBIT BE GRANTED CONFIDENTIAL TREATMENT UNDER RULE 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED

EXECUTION VERSION

MASTER CLINICAL TRIAL COLLABORATION AND SUPPLY AGREEMENT

This MASTER CLINICAL TRIAL COLLABORATION AND SUPPLY AGREEMENT (this "**Agreement**"), made as of May 29, 2018 (the "**Effective Date**"), is by and between Regeneron Pharmaceuticals, Inc., having a place of business at 777 Old Saw Mill River Road, Tarrytown, NY 10591 ("**Regeneron**"), and Replimune Group Inc. having a place of business at 18 Commerce Way, Woburn MA 01801 ("**Replimune**"). Regeneron and Replimune are each referred to herein individually as a "**Party**" and collectively as the "**Parties**".

RECITALS

- A. Regeneron holds intellectual property rights with respect to the Regeneron Compound (as defined below).
- B. Replimune holds intellectual property with respect to the Replimune Compound (as defined below).
- C. Replimune is developing the Replimune Compound for the treatment of certain tumor types.
- D. Regeneron is developing the Regeneron Compound for the treatment of certain tumor types.

F. The Parties now wish to undertake one or more Combination Clinical Trials (as defined below) in which the Replimune Compound and the Regeneron Compound would be dosed concurrently or in combination to treat various types of cancer (each, a "**Study**", as defined below). For each such Study, the Parties are to complete and enter into a Study Plan (as defined below), which, among other items, identifies the Party that is the Sponsoring Party for such Study and includes the Protocol, Budget, Sample Testing and Clinical Obligations Schedule (each as defined below) for such Study.

G. Regeneron and Replimune, consistent with the terms of this Agreement, desire to collaborate as more fully described herein, including by providing the Regeneron Compound and the Replimune Compound for each Study.

NOW, THEREFORE, in consideration of the premises and of the following mutual promises, covenants and conditions, the Parties, intending to be legally bound, mutually agree as follows:

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1. <u>Definitions.</u>

For all purposes of this Agreement, the capitalized terms defined in this Article 1 and throughout this Agreement shall have the meanings herein specified.

1.1 "Affiliate" means, with respect to either Party, a firm, corporation or other entity which directly or indirectly owns or controls said Party, or is owned or controlled by said Party, or is under common ownership or control with said Party. The word "**control**" means (i) the direct or indirect ownership of fifty percent (50%) or more of the outstanding voting securities of a legal entity, or (ii) possession, directly or indirectly, of the power to direct the management or policies of a legal entity, whether through the ownership of voting securities, contract rights, voting rights, corporate governance or otherwise.

1.2 "Agreement" means this agreement, as amended by the Parties from time to time, and as set forth in the preamble.

1.3 **"Applicable Law"** means all federal, state, local, national and regional statutes, laws, rules, regulations and directives applicable to a particular activity hereunder, including performance of clinical trials, medical treatment and the processing and protection of personal and medical data, that may be in effect from time to time, including those promulgated by the United States Food and Drug Administration (**"FDA"**), the European Medicines Agency (**"EMA"**) and any successor agency to the FDA or EMA or any agency or authority performing some or all of the functions of the FDA or EMA in any jurisdiction outside the United States or the European Union (each a "**Regulatory Authority**" and collectively, "**Regulatory Authorities**"), and including without limitation cGMP and GCP (each as defined below); all data protection requirements such as those specified in the EU Data Protection Directive and the regulations issued under the United States Health Insurance Portability and Accountability Act of 1996 ("**HIPAA**"); export control and economic sanctions regulations which prohibit the shipment of United States-origin products and technology to certain restricted countries, entities and individuals; anti-bribery and anti-corruption laws pertaining to interactions with government agents, officials and representatives; laws and regulations governing payments to healthcare providers; and any United States or other country's or jurisdiction's successor or replacement statutes, laws, rules, regulations and directives relating to the foregoing.

- 1.4 **"Audit Arbitrator**" has the meaning set forth in Section 7.3.3.
- 1.5 **"Budget**" has the meaning set forth in Section 7.1.

1.6 **"Business Day**" means any day other than a Saturday, Sunday or any public holiday in the country where the applicable obligations are to be performed.

1.7 "Calendar Quarter" means a three-month period beginning on January, April, July or October 1st.

1.8 "Calendar Year" means a one-year period beginning on January 1st and ending on December 31st.

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1.9 **"cGMP**" means the current Good Manufacturing Practices officially published and interpreted by EMA, FDA and other applicable Regulatory Authorities that may be in effect from time to time and are applicable to the Manufacture of the Compounds.

1.10 **"Change of Control**" means with respect to a Party: (1) the sale of all or substantially all of such Party's assets or business relating to this Agreement; (2) a merger, reorganization or consolidation involving a Party in which the voting securities of such Party outstanding immediately prior thereto cease to represent at least fifty percent (50%) of the combined voting power of the surviving entity immediately after such merger, reorganization or consolidation; or (3) a person or entity, or group of persons or entities, acting in concert acquire more than fifty percent (50%) of the voting equity securities or management control of the Party.

1.11 "Clinical Data" means, for each Study, the data and results generated under such Study, including such Study's Sample Testing Results.

1.12 "Clinical Supply Quality Agreement" means a Clinical Supply Quality Agreement the Parties agree to enter into for a particular Study.

1.13 "Clinical Obligations Schedule" means, for each Study, the schedule attached to the Study Plan for such Study setting forth the obligations of the Parties in connection with the conduct of the applicable Study.

1.14 "Collaboration Know-How" has the meaning set forth in Section 10.1.1.

1.15 **"Combination**" means the use or method of using the Replimune Compound and the Regeneron Compound in concomitant or sequential administration.

1.16 **"Combination Clinical Trial"** means a clinical trial to be conducted under this Agreement for the Combination.

1.17 "Competitive Study" has the meaning set forth in Section 2.7.

1.18 **"Compounds**" means the Replimune Compound and the Regeneron Compound. A "**Compound**" means either the Replimune Compound or the Regeneron Compound, as applicable.

1.19 **"Confidential Information**" means any information, Know-How or other proprietary information or materials furnished to one Party by the other Party in connection with this Agreement or a Study Plan, except to the extent that it can be established by the receiving Party that such information or materials: (a) were already known to the receiving Party, other than under an obligation of confidentiality, at the time of disclosure by the disclosing Party as demonstrated by competent business records; (b) were generally available to the public or otherwise part of the public domain at the time of its disclosure to the receiving Party; (c) became generally available to the public or otherwise part of the public domain after their disclosure and other than through any act or omission of the receiving Party in breach of this Agreement; (d) were disclosed to the receiving Party by a Third Party who had no obligation to the disclosing Party not to disclose such information to others; or (e) were subsequently developed by the

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receiving Party without use of or reference to the Confidential Information as demonstrated by competent business records.

1.20 "**Continuing Party**" has the meaning set forth in Section 10.1.2.

1.21 "CTA" means an application to a Regulatory Authority for purposes of requesting the ability to start or continue a clinical trial.

1.22 "**Development Costs**" means, []*, in each case, that are incurred as an expense in accordance with such Party's accounting standards (consistently applied) and consistent with the applicable Study Plan and Budget for such Study; provided that in all cases, Development Costs []*. For clarity, Development Costs will be calculated separately for each Study.

1.23 **"Development FTE Cost**" means, for a given period, the Development FTE Rate multiplied by the number of FTEs in such period utilized in connection with a Study (and other activities related thereto as set forth in the Study Plan, including regulatory activities).

1.24 "Development FTE Rate" means a rate of []*; provided that, starting January 1, 2019, []* (as of January 1 of a given Calendar Year).

1.25 **"Disposition Package**" has the meaning set forth in Section 8.7.1.

1.26 "**Dispute**" has the meaning set forth in Section 21.1.

1.27 **"Effective Date**" has the meaning set forth in the preamble.

1.28 "EMA" has the meaning set forth in the definition of Applicable Law.

1.29 []*

1.30 **"Final Study Report**" means, for each Study, the final written report on the results of such Study as prepared by the Responsible Party for such Study.

1.31 **"First Site Ready**" means, for a Study, the date on which the first clinical site has all deliverables in place to support patient enrollment in such Study.

1.32 **"FDA**" has the meaning set forth in the definition of Applicable Law.

1.33 **"FTE**" means []* devoted to or in support of the conduct of a Study under a Study Plan and that is carried out by one or more employees of Replimune or Regeneron (or their respective Affiliates), as applicable, or any prorated portion thereof.

1.34 "**GCP**" means the Good Clinical Practices officially published by EMA, FDA and the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) that may be in effect from time to time and are applicable to the testing of the Compounds.

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1.35 **"Government Official**" means: (a) any officer or employee of a government or any department, agency or instrument of a government; (b) any person acting in an official capacity for or on behalf of a government or any department, agency, or instrument of a government; (c) any officer or employee of a company or business owned in whole or part by a government; (d) any officer or employee of a public international organization such as the World Bank or United Nations; (e) any officer or employee of a political party or any person acting in an official capacity on behalf of a political party; and/or (f) any candidate for political office; who, when such Government Official is acting in an official capacity, or in an official decision-making role, has responsibility for performing regulatory inspections, government authorizations or licenses, or otherwise has the capacity to take decisions with the potential to affect the business of either of the Parties.

1.36 "HIPAA" has the meaning set forth in the definition of Applicable Law.

1.37 **"IND**" means the Investigational New Drug Application filed or to be filed with the FDA as described in Title 21 of the U.S. Code of Federal Regulations, Part 312, and the equivalent application in the jurisdictions outside the United States, including an "Investigational Medicinal Product Dossier" filed or to be filed with the EMA.

1.38 "Inventions" means all inventions and discoveries that are made or conceived in the performance of a Study.

1.39 "Jointly Owned Invention" has the meaning set forth in Section 10.1.1.

1.40 "Joint Patent Application" has the meaning set forth in Section 10.1.2.

1.41 "Joint Patent" means a patent that issues from a Joint Patent Application.

1.42 **"Know-How"** means any proprietary invention, innovation, improvement, development, discovery, computer program, device, trade secret, method, know-how, process, technique or the like, including manufacturing, use, process, structural, operational and other data and information, whether or not written or otherwise fixed in any form or medium, regardless of the media on which contained and whether or not patentable or copyrightable, that is not generally known or otherwise in the public domain.

1.43 "Liability" has the meaning set forth in Section 14.2.1.

1.44 **"Manufacture," "Manufactured,"** or **"Manufacturing"** means all stages of the manufacture of a Compound, including planning, purchasing, manufacture, processing, compounding, storage, filling, packaging, waste disposal, labeling, leafleting, testing, quality assurance, sample retention, stability testing, release, dispatch and supply, as applicable.

1.45 "Manufacturer's Release" or "Release" has the meaning ascribed to such term in the Clinical Supply Quality Agreement.

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1.46 **"Manufacturing Site**" means the facilities where a Compound is Manufactured by or on behalf of a Party, as such Manufacturing Site may change from time to time in accordance with Section 8.6.

1.47 **"Non-Conformance**" means, with respect to a given unit of Compound, an event that deviates from (i) the approved Specifications for such Compound; (ii) the applicable Clinical Supply Quality Agreement; and (iii) all Applicable Law, including cGMP and health, safety and environmental protections.

1.48 "Non-filing Party" has the meaning set forth in Section 10.1.2.

1.49 **"Non-Responsible Party**" means, with respect to a right or obligation under this Agreement, including any Study Plan, the Party that is not the Responsible Party with respect to such right or obligation.

1.50 "Non-Sponsor Party" means, for each Study, the Party that is not the Sponsor of such Study.

1.51 "Oncolytic Virus" means []*

1.52 **"Opting-Out Party**" has the meaning set forth in Section 10.1.2.

1.53 **"Other Party's Compound**" means, with respect to Replimune, the Regeneron Compound, and with respect to Regeneron, the Replimune Compound.

1.54 **"Party**" has the meaning set forth in the preamble.

1.55 "PD-1 Antagonist" means []*

1.56 **"Pharmacovigilance Agreement**" means a pharmacovigilance agreement the Parties agree to enter into to cover a particular Study.

1.57 **"Protocol**" means, for each Study, the written documentation that describes such Study and sets forth specific activities to be performed as part of the conduct of such Study. The final Protocol shall be agreed as set forth in Section 4.1.

1.58 **"Regeneron Compound**" means []* that targets []* and is formulated for IV administration. For the purposes of Sections 2.3, 2.5, 3.3 and Article 8, reference to the Regeneron Compound shall also include any []*.

1.59 "Regeneron Compound Specific Clinical Data" has the meaning set forth in Section 3.7.

1.60 **"Regulatory Approvals**" means, with respect to a compound and a country, any and all permissions (other than the Manufacturing approvals) required to be obtained from Regulatory Authorities and any other competent authority for the development, registration,

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importation, use (including use in clinical trials), distribution, sale and marketing of such compound in such country, including any pricing or reimbursement approvals.

1.61 "**Regulatory Authorities**" has the meaning set forth in the definition of Applicable Law.

1.62 **"Replimune Compound"** means any of Replimune's proprietary oncolytic viruses. For the purposes of Sections 2.3, 2.5, 3.3 and Article 8, reference to the Replimune Compound shall also include any RP-1 placebo that is part of any Study.

1.63 "Replimune Compound Specific Clinical Data" has the meaning set forth in Section 3.7.

1.64 **"Responsible Party**" means, for each Study, that Party expressly designated in Articles 1 through 25 of this Agreement or in the applicable Study Plan for such Study as the responsible party with respect to a particular activity or obligation in connection with the conduct of such Study. Unless explicitly stated otherwise in this Agreement or in the applicable Study Plan, the Responsible Party shall be the Sponsoring Party.

1.65 "Samples" means, for each Study, the samples described in the applicable Study Plan for such Study.

1.66 **"Sample Testing**" means, for each Study, the studies to be performed by each Party using the applicable Samples for such Study as set forth in the applicable Study Plan.

1.67 **"Sample Testing Results**" means, for each Study, those results arising from the Sample Testing that are to be shared between Regeneron and Replimune, as set forth in the applicable Study Plan for such Study.

1.68 "**Specifications**" means, with respect to a Compound to be used in a Study, the set of requirements for such Compound as set forth in the Clinical Supply Quality Agreement covering such Study.

1.69 **"Sponsoring Party**" means, for each Study, the sponsor of such Study as the term "sponsor" is defined in Title 21 C.F.R. Part 312.3(b). Each Study Plan for a Study will expressly state which of the Parties shall be the Sponsoring Party for such Study.

1.70 **"Study**" means each clinical trial to be conducted under this Agreement pursuant to an executed Study Plan for the concomitant or sequenced administration of the Regeneron Compound and the Replimune Compound as outlined in the Protocol that is attached to the applicable Study Plan, which Protocol may be amended by the JDC in accordance with Section 4.1. Each Study will be a Combination Clinical Trial in subjects with the tumor type identified in the applicable Study Plan.

1.71 **"Study Completion**" has the meaning set forth in Section 3.9.

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1.72 "Study Effective Date" means the effective date of the applicable Study Plan as set forth on such Study Plan.

1.73 **"Study Plan**" means, for each Study, the plan substantially in the form of <u>Appendix A</u>, including all Exhibits thereto, that is completed and entered into by the Parties for such Study as further described in Section 2.1.

1.74 "[]*" has the meaning []*.

1.75 **"Taxes**" has the meaning set forth in []*.

1.76 **"Toxicity and Safety Data"** means all clinical adverse event information and/or patient-related safety data, as more fully described in the Pharmacovigilance Agreement.

1.77 "Third Party" means any person or entity other than Replimune, Regeneron or their respective Affiliates.

2. <u>Scope of the Agreement</u>.

2.1 The Parties intend to undertake one or more Studies under this Agreement to evaluate the Combination in subjects with certain cancer or tumor types. Prior to the commencement of each Study, the Parties shall complete and enter into a Study Plan for such Study substantially in the form of <u>Appendix A</u>. The Study Plan for each Study shall be sequentially numbered and shall set forth: (a) the Sponsoring Party for such Study; (b) the Project Manager for each Party; (c) the Protocol for such Study, or a Protocol synopsis if the final Protocol has not been agreed to by the Parties prior to the Study Effective Date; (d) a schedule setting forth the quantities and timelines for the supply of each Party's Compound for such Study as further described in Article 8; (e) the applicable Samples to be obtained and Sample Testing for such Study; (f) the Clinical Obligations Schedule for such Study; (g) the budget and cost-sharing arrangement for such Study, if applicable, as further described in Section 4.1; (h) the Study Effective Date for such Study Plan; and (i) any mutually agreed upon deviations from the terms of this Agreement, or additional terms that are necessary for the performance of such Study by the Parties as determined by the JDC. Each Study Plan. In the event of conflict between the terms described in Articles 1 through 25 of this Agreement and the terms of any Study Plan, the terms of Articles 1 through 25 of this Agreement in such Study Plan.

2.2 Each Party shall contribute to each Study such resources as are necessary to fulfill its obligations as set forth in this Agreement or any Study Plan.

2.3 Each Party shall grant and hereby grants the other Party a non-exclusive license under its intellectual property and the intellectual property of its Affiliates, for the sole purpose of the other Party's performance of activities under an in accordance with the relevant Study Plan.

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2.4 Each Party agrees to act in good faith in performing its obligations under this Agreement and shall notify the other Party as promptly as possible in the event of any Manufacturing or other delay that is likely to adversely affect supply of its Compound or timely performance of its obligations as contemplated by this Agreement or any Study Plan.

2.5 Replimune agrees to Manufacture and supply the Replimune Compound for purposes of each Study as set forth in Article 8, and Replimune hereby represents and warrants to Regeneron that, at the time of Delivery of the Replimune Compound, such Replimune Compound shall have been Manufactured and supplied in compliance with: (i) the Specifications for the Replimune Compound; (ii) the applicable Clinical Supply Quality Agreement; and (iii) all Applicable Law, including cGMP and health, safety and environmental protections. Regeneron agrees to Manufacture and supply the Regeneron Compound for purposes of each Study as set forth in Article 8, and Regeneron hereby represents and warrants to Replimune that, at the time of Delivery of the Regeneron Compound, such Regeneron Compound shall have been Manufactured and supplied in compliance with: (a) the Specifications for the Regeneron Compound; (b) the Clinical Supply Quality Agreement; and (c) all Applicable Law, including cGMP and health, safety and environmental protections. Without limiting the foregoing, each Party is responsible for obtaining all regulatory approvals (including facility licenses) that are required to Manufacture its Compound in accordance with Applicable Law (provided that for clarity, the Sponsoring Party shall be responsible for obtaining Regulatory Approvals for each Study as set forth in Section 3.5).

2.6 Each Party shall have the right to subcontract any portion of its obligations hereunder to subcontractors, provided that the subcontracting Party shall consult with the JDC regarding the use of such Third Parties in the performance of such obligations (but for clarity, shall not have the right to approve such Third Parties), and further provided that such Party shall remain solely and fully liable for the performance of such subcontractors. Each Party shall ensure that each of its subcontractors performs its obligations pursuant to the terms of this Agreement, including the Appendices attached hereto. Each Party shall use reasonable efforts to obtain and maintain copies of documents relating to the obligations performed by such subcontractors that are held by or under the control of such subcontractors and that are required to be provided to the other Party under this Agreement. The non-Sponsoring Party, through the JDC shall have the right to review and comment on (but for clarity, shall not have the right to approve) the site template used by the Sponsoring Party or any clinical research organization used by the Sponsoring Party for the Study.

2.7 Third Party Collaborations and []*.

(a) With respect to (i) the []* which is agreed to be in Cutaneous Squamous Cell Carcinoma and set forth in the Study Plan and will be mutually agreed to promptly following the Effective Date in accordance with Section 4.1 []*, Replimune will not except as otherwise provided in this Section 2.7(a), []* for such Study (each of (i), (ii), (iii) and (iv), a "Replimune Competitive Study"). Replimune's performance of a study for the use of the Replimune Compound and []* shall not be deemed to be a Replimune Competitive Study if []*

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in the conduct of such study. []*.

(b) With respect to (i) the []* which is agreed to be in Cutaneous Squamous Cell Carcinoma and set forth in the Study Plan and will be mutually agreed to promptly following the Effective Date in accordance with Section 4.1 and []* for such Study (each of (i), (ii), (iii) and (iv), a "**Regeneron Competitive Study**"). Regeneron's performance of a study for the use of the Regeneron Compound and []* in concomitant or sequential administration shall not be deemed to be a Regeneron Competitive Study []* in the conduct of such study. []*.

(c) With respect to each Study set forth under a Study Plan, during the period commencing with the date of []* and ending []* thereafter, Replimune will not initiate a Replimune Competitive Study and Regeneron will not initiate a Regeneron Competitive Study (such studies referred to hereafter as to each Party as a "**Competitive Study**"), and neither Party will agree to perform a Competitive Study, or discuss a Competitive Study with a Third Party without complying with this Section 2.7. In the event a Party wishes to enter into exclusive negotiations with the other Party regarding []*, such Party so desiring to negotiate shall provide the other Party with notice thereof within []*. If such Party fails to delivers such notice to the other Party within such []*, then the other Party shall thereafter be free to engage in []* negotiations with Third Parties for, and enter into a written agreement for []* with any Third Party without further obligations under this Section 2.7(c). In the event the Party so desiring to negotiate delivers such notice thereof within the []* period, the Parties will engage in good faith negotiations, and each Party will permit the other Party to conduct and facilitate the other Party's conduct of, technical due diligence for a period of up to []* after []* ("Exclusive Negotiation Period") in an attempt to agree upon the terms and conditions pursuant to which the Parties shall promptly thereafter (but in any event within []* after agreement on such terms and conditions) enter into a definitive agreement reflecting such terms and the Exclusive Negotiation Period shall continue until the Parties have executed such definitive agreement. If the Parties fail to reach agreement

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during the Exclusive Negotiation Period on terms and conditions pursuant to which the Parties []*, then each Party shall thereafter be free to engage in negotiations with Third Parties for, and enter into agreements with Third Parties []* without further obligations under this Section 2.7(c).

(d) For clarity, nothing in Section 2.7(a), (b), and (c) shall be deemed to restrict Replimune or Regeneron from entering into a transaction with any Third Party to license, sell or otherwise grant or transfer, including by option, rights in or to further develop or commercialize the Replimune Compound or the Regeneron Compound.

(e) This Agreement does not create any obligation on the part of Regeneron to provide the Regeneron Compound for any activities other than each Study, nor does it create any obligation on the part of Replimune to provide the Replimune Compound for any activities other than each Study, and except as set forth in Section 2.7(a), (b), and (c), nothing in this Agreement shall (A) prohibit either Party from performing studies relating to its own Compounds, either individually or in combination with any other compound or product, in any therapeutic area, or (B) create an exclusive relationship between the Parties with respect to any Compound, including the Regeneron Compound and the Replimune Compound.

3. <u>Conduct of Each Study</u>.

3.1 Each Study Plan for a Study will expressly state which of the Parties shall be the Sponsoring Party for such Study. The Sponsoring Party shall hold the IND relating to such Study.

3.2 The Sponsoring Party shall ensure that such Study is performed in accordance with this Agreement, the Study Plan, the Protocol and all Applicable Law, including GCP, provided, however, that to the extent the Non-Sponsor Party is the Responsible Party for a particular clinical activity in accordance with the Clinical Obligations Schedule for a particular Study, it shall ensure such activities are performed in accordance with this Agreement, the Study Plan, the Protocol and all Applicable Law, including GCP.

3.3 The Parties hereby agree to use commercially reasonable, good faith efforts in executing their obligations under this Agreement and each Study Plan, including a Party's supply obligations under Article 8.

3.4 For each Study, the Sponsoring Party for such Study shall ensure that all directions in relation to its obligations as such Study's sponsor from any Regulatory Authority and/or ethics committee with jurisdiction over such Study are followed. Further, for each Study, the Sponsoring Party for such Study, in working with the Non-Sponsor Party, shall ensure that all Regulatory Approvals from any Regulatory Authority and/or ethics committee with jurisdiction over such Study.

3.5 <u>Regulatory Interactions and Filings</u>.

(a) Each Party (the "**Granting Party**") grants to the other Party (the "**Referencing Party**") a nonexclusive, non-transferable (except in connection with a permitted

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assignment of this Agreement) "right of reference" (as defined in US FDA 21 CFR 314.3(b)), or similar "right of reference" as defined in applicable regulations in the relevant jurisdiction outside the U.S., with respect to the Regeneron Compound Specific Clinical Data (in the case where Regeneron is the Granting Party) and/or Replimune Compound Specific Clinical Data (in the case where Replimune is the Granting Party), solely as necessary for such Referencing Party to prepare, submit and maintain regulatory submissions related to such Referencing Party's Compound and Regulatory Approvals related thereto for use in the Combination, as and to the extent permitted in accordance with Section 3.7. Further, the Granting Party shall provide to the Referencing Party a cross-reference letter or similar communication to the applicable Regulatory Authority to effectuate such right of reference. Notwithstanding anything to the contrary in this Agreement, neither Party shall have any right to access the other Party's CMC data with respect to such Other Party's Compound. Regeneron will authorize FDA and other applicable Regulatory Authorities to cross-reference the appropriate Regeneron Compound INDs and CTAs to provide data access to Replimune sufficient to support conduct of each Study. Replimune will authorize FDA and other applicable Regulatory Authorities to cross-reference the appropriate Replimune Compound INDs and CTAs to provide data access to Regeneron sufficient to support conduct of each Study.

(b) For so long as Replimune has not obtained Regulatory Approval for the Replimune Compound as a monotherapy in the United States and the European Union, Replimune shall use commercially reasonable efforts to prepare, submit and file for Regulatory Approval to the FDA and the European Medicines Agency for the Combination in the indication that was evaluated under a given Study, assuming such Study results adequately support such a filing, subject to Regeneron's consent rights in Section 3.7. If Replimune determines that it does not wish to prepare, submit and file for Regulatory Approval for the Combination as set forth in the previous sentence, it shall promptly provide a written explanation to Regeneron outlining the scientific, clinical and/or commercial rationale for not doing so and Replimune shall consider any comment made by Regeneron in good faith in determining whether such decision by Replimune is consistent with its obligation to use such commercially reasonable efforts.

(c) If Replimune is the Sponsoring Party, Regeneron shall have the right (but no obligation) to participate in any discussions between Replimune and any Regulatory Authority regarding matters related specifically to either the Regeneron Compound or the Combination in connection with each Study, and to the extent reasonably practicable, Replimune shall provide sufficient advance notice to Regeneron of any such discussions to allow inclusion of questions from Regeneron. Regeneron shall have the right, (but no obligation) to include questions to any Regulatory Authority in connection with either the Regeneron Compound or the Combination in connection with each Study. If Replimune receives any comments or other inquiries from a Regulatory Authority that pertain to the Combination or the Regeneron Compound, Replimune shall provide such comments to Regeneron, and Regeneron shall provide its response to Replimune no later than []* from the date that Regeneron receives such comments or other inquiries from a Regulatory Authority that pertain to the Combination, but not specifically to the Regeneron Compound, Replimune will consider in good faith Regeneron's reasonable comments. If such comments or other inquiries pertain specifically to the Regeneron Compound, Regeneron will promptly review and respond within the Regeneron Response Period and Replimune will forward such response to

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the Regulatory Authority on Regeneron's behalf. In the event that it will take Regeneron more than []* to provide a response, Regeneron will notify Replimune promptly (but no later than the end of the Regeneron Response Period), and provide Replimune with the reason the response cannot be provided within the Regeneron Response Period and with the timeframe within which Regeneron will provide its response, in which case Replimune will make reasonable efforts to accommodate Regeneron's reasonable request for additional time. If Regeneron does not provide such response or notice within the Regeneron Response Period, then Replimune may proceed to respond to the applicable Regulatory Authority in Replimune's sole good faith discretion. In any event, Regeneron shall endeavor to promptly provide such response to Replimune so that Replimune may provide a timely response to the Regulatory Authority. With respect to any comments or other inquiries from a Regulatory Authority regarding a Study that pertain specifically to the Regeneron Compound, Regeneron shall also be permitted to respond directly to such Regulatory Authority; provided however, that prior to providing its response to such Regulatory Authority, Regeneron shall (i) notify Replimune in writing within the applicable Regeneron Response Period that Regeneron intends to respond directly to such Regulatory Authority; (ii) provide Replimune with Regeneron's proposed response in writing; (iii) consider in good faith Replimune's reasonable comments thereto; and (iv) provide Replimune with a final copy of Regeneron's response for Replimune's records; provided, however, that Regeneron shall have the right to redact any proprietary information that is not related to the applicable Study or the Combination (such as CMC or critical material information). Subject to the conditions set forth in the foregoing sentence, if Regeneron elects to respond directly to such Regulatory Authority, Regeneron shall be responsible for providing its response within the deadline prescribed by such Regulatory Authority (if none, Regeneron shall nonetheless provide such response promptly). Unless otherwise agreed in the applicable Clinical Obligations Schedule, and. except for direct responses from Regeneron in accordance with this Section 3.5(b), Replimune shall conduct communications with Regulatory Authorities relating to each Study for which Replimune is the Sponsoring Party.

(d) If Regeneron is the Sponsoring Party, Replimune shall have the right (but no obligation) to participate in any discussions between Regeneron and any Regulatory Authority regarding matters related specifically to either the Combination or the Replimune Compound in connection with each Study, and to the extent reasonably practicable, Regeneron shall provide sufficient advance notice to Replimune of any such discussions to allow inclusion of questions from Replimune. Replimune shall have the right, (but no obligation) to include questions to any Regulatory Authority in connection with either the Replimune Compound or the Combination in connection with each Study. If Regeneron receives any comments or other inquiries from a Regulatory Authority that pertain to the Combination or the Replimune Compound, Regeneron shall promptly provide such comments to Replimune, and Replimune shall provide its response to Regeneron no later than []* from the date that Replimune receives such comments or other inquiries from Regeneron or such shorter period as may be required by such Regulatory Authority ("**Replimune Response Period**"). For all comments or inquiries that pertain to the Combination, but not specifically to the Replimune Compound, Regeneron will consider in good faith Replimune's reasonable comments. If such comments or other inquiries pertain specifically to the Replimune Compound, Replimune will promptly review and respond within the Replimune Response Period and Regeneron will forward such response to the Regulatory Authority on Replimune's behalf. In the event that it will take Replimune more than []* to

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provide a response, Replimune will notify Regeneron promptly (but no later than the end of the Replimune Response Period), and provide Regeneron with the reason the response cannot be provided within the Replimune Response Period and with the timeframe within which Replimune will provide its response, in which case Regeneron will make reasonable efforts to accommodate Replimune's reasonable request for additional time. If Replimune does not provide such response or notice within the Replimune Response Period, then Regeneron may proceed to respond to the applicable Regulatory Authority in Regeneron's sole good faith discretion. In any event, Replimune shall endeavor to promptly provide such response to Regeneron so that Regeneron may provide a timely response to the Regulatory Authority. With respect to any comments or other inquiries from a Regulatory Authority regarding a Study that pertain specifically to the Replimune Compound, Replimune shall also be permitted to respond directly to such Regulatory Authority; provided however, that prior to providing its response to such Regulatory Authority, Replimune shall (i) notify Regeneron in writing within the applicable Replimune Response Period that Replimune intends to respond directly to such Regulatory Authority; (ii) provide Regeneron with Replimune's proposed response in writing; (iii) consider in good faith Regeneron's reasonable comments thereto; and (iv) provide Regeneron with a final copy of Replimune's response for Regeneron's records; provided, however, that Replimune shall have the right to redact any proprietary information that is not related to such Study or the Combination (such as CMC or critical material information). Subject to the conditions set forth in the foregoing sentence, if Replimune elects to respond directly to such Regulatory Authority, Replimune shall be responsible for providing its response within the deadline prescribed by such Regulatory Authority (if none, Replimune shall nonetheless provide such response promptly). Unless otherwise agreed in the applicable Clinical Obligations Schedule, and except for direct responses from Replimune in accordance with this Section 3.5(d)), Regeneron shall have the right to conduct communications with Regulatory Authorities relating to each Study for which Regeneron is the Sponsoring Party.

(e) Each Party shall maintain reports and all related documentation in good scientific manner and in compliance with Applicable Law in connection with each Study. Each Party shall provide to the other Party all Study information and documentation reasonably requested by such Party to enable such Party to (i) comply with any of its legal, regulatory and/or contractual obligations, or any request by any Regulatory Authority, related to the Regeneron Compound, the Replimune Compound, or the Combination, as applicable, and (ii) determine whether such Study has been performed in accordance with this Agreement.

3.6 The Responsible Party shall provide to the other Party copies of all Clinical Data (except the Sample Testing Results which are separately covered by Section 3.8), in electronic form or other mutually agreeable alternate form and on mutually agreeable timelines. The Responsible Party shall require that Study investigators obtain patient authorizations and consents required under HIPAA, the EU Data Protection Directive or any other similar Applicable Law in connection with each Study, to permit such sharing of Clinical Data with the other Party.

3.7 All Clinical Data from any Regeneron Compound monotherapy arm of a Study or any other Clinical Data specific to the Regeneron Compound from a Study shall be owned by Regeneron ("**Regeneron Compound Specific Clinical Data**") and Replimune shall assign and hereby assigns to Regeneron, all of Replimune's interest in Regeneron Compound Specific

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Clinical Data. All Clinical Data from any Replimune Compound monotherapy arm of a Study or any other Clinical Data specific to the Replimune Compound from a Study shall be owned by Replimune ("Replimune Compound Specific Clinical Data") and Regeneron shall assign and hereby assigns to Replimune, all of Regeneron's interest in Replimune Compound Specific Clinical Data. All Clinical Data, generated under each Study, except for Regeneron Compound Specific Clinical Data, Replimune Compound Specific Clinical Data and Sample Testing Results, shall be jointly owned by Replimune and Regeneron. With respect to a given Study, and notwithstanding the foregoing or anything to the contrary in this Agreement, (i) (a) Replimune and its Affiliates shall have the right, without the consent of, or any obligation to account to Regeneron, following Regulatory Approval of the Regeneron Compound as a monotherapy or for use in combination with another active agent, in each case in the indication that is being evaluated under such Study, to use all Regeneron Compound Specific Clinical Data from such Study to make regulatory filings, meet regulatory requirements and seek Regulatory Approval for the Combination and (b) if Regulatory Approval of the Regeneron Compound as a monotherapy or for use in combination with another active agent in each case in the indication that is being evaluated under such Study has not been achieved, Regeneron's written consent shall be required for Replimune to use Regeneron Compound Specific Clinical Data from such Study to make regulatory filings, meet regulatory requirements and seek Regulatory Approval for the Combination, such consent not to be unreasonably withheld, conditioned or delayed; and (ii) (a) Regeneron and its Affiliates shall have the right, without the consent of, or any obligation to account to Replimune, following Regulatory Approval of the Replimune Compound as a monotherapy or for use in combination with any other active agent in each case in the indication that is being evaluated under such Study, to use all Replimune Compound Specific Clinical Data from such Study to make regulatory filings, meet regulatory requirements and seek Regulatory Approval for the Combination, including the filing of any amendment or supplement to its Regulatory Approval of the Regeneron Compound, in each case, where permitted by and in accordance with Applicable Law and (b) if Regulatory Approval of the Replimune Compound as a monotherapy or for use in combination with another active agent in each case in the indication that is being evaluated under such Study has not been achieved, Replimune's written consent shall be required for Regeneron to use Replimune Compound Specific Clinical Data from such Study to make regulatory filings, meet regulatory requirements and seek Regulatory Approval for the Combination, including the filing of any amendment or supplement to its Regulatory Approval of the Regeneron Compound, in each case, where permitted by and in accordance with Applicable Law, such consent not to be unreasonably withheld, conditioned or delayed provided that nothing in the foregoing clauses (i) and (ii) is intended or shall be construed as granting Replimune any right or license, expressly or impliedly, to make, have made, use, sell, offer for sale, or import the Regeneron Compound, or as granting Regeneron any right or license, expressly or impliedly, to make, have made, use, sell, offer for sale, or import the Replimune Compound. For the avoidance of doubt, Replimune shall not be able to use the Regeneron Compound Specific Clinical Data, and Regeneron shall not be able to use the Replimune Compound Specific Clinical Data, in each case for any purpose whatsoever other than as expressly specified in this Agreement, without the prior written consent of the other Party, subject to the rights of each Party to disclose such data to the extent permitted under Article 9. Regeneron Compound Specific Clinical Data shall be the Confidential Information of Regeneron and Replimune Compound Specific Clinical Data shall be the Confidential Information of Replimune. Notwithstanding the above and without limiting Section 2.7, these restrictions set

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forth in this Section 3.7 and the restrictions set forth in Article 9, shall no longer apply to any portion of Clinical Data that has been made available to the public in accordance with this Agreement. Notwithstanding the above or anything to the contrary herein, either Party may share any Clinical Data as required by a Regulatory Authority or as may otherwise be required by Applicable Law. Notwithstanding anything to the contrary herein, to the extent Clinical Data includes Toxicity and Safety Data, and where because of its severity, frequency or lack of reversibility either Party meds to utilize such Toxicity and Safety Data with respect to its respective Compound or of the Combination in order to ensure patient safety, such Party may share such Toxicity and Safety Data with Third Parties.

3.8 Each Party shall use the Samples only for Sample Testing. The Sponsoring Party shall own Sample Testing Results unless otherwise set forth in the applicable Study Plan. The Sponsoring Party shall provide to the Non-Sponsoring Party the Sample Testing Results for the Sample Testing conducted by or on behalf of the Sponsoring Party, in electronic form or other mutually agreeable alternate form and on the timelines specified in the applicable Study Plan. The Non-Sponsoring Party may use the Sponsoring Party's Sample Testing Results, only for the purposes of (i) seeking Regulatory Approval of (A) its respective Compound as a monotherapy (provided that the Non-Sponsoring Party would not have the right to use any Sponsoring Party's Sample Testing Results that solely relate to that Sponsoring Party's Compound in seeking Regulatory Approval of such Non-Sponsoring Party's Compound), or the Combination, to the extent permitted under Section 3.7 and/or (B) any companion diagnostic to any pharmaceutical product containing its respective Compound for use as a monotherapy or the Combination, and (ii) filing and prosecuting patent applications for Joint Inventions and enforcing any resulting patents in accordance with Article 10; provided, however, that these restrictions shall no longer apply once the Sample Testing Results or portions thereof are available to the public in accordance with this Agreement. Further, the permitted uses that apply to jointly owned Clinical Data as set forth in the last sentence of Section 3.7 shall apply with respect to Sample Testing Results that are jointly owned to the extent set forth in the applicable Study Plan.

3.9 Within []* following Study Completion for each Study, and in accordance with the timeframes set forth in this Section 3.9, the Responsible Party with respect to preparing the Final Study Report for such Study shall provide the Non-Responsible Party with an electronic draft of the Final Study Report for such Study, for the Non-Responsible Party to provide comments to the Responsible Party within []* of its receipt of the draft of such Final Study Report. The Responsible Party shall consider in good faith such comments and, at either Party's reasonable request, the Parties shall meet in person or via teleconference within []* after the Responsible Party's receipt of such comments to discuss such comments in good faith. The Responsible Party shall consider in good faith aversion of each Final Study Report within []* of the Responsible Party's receipt of the Non-Responsible Party shall consider in good faith any further comments or a meeting between the Parties to discuss such comments, whichever is later. The Responsible Party shall consider in good faith any further comments of the Non-Responsible Party, and each Final Study Report shall not be deemed final until the Parties have mutually so agreed. In the event that the Parties are unable to agree upon a Final Study Report, the matter will be escalated to the Replimune Chief Medical Officer and the Regeneron Senior Vice President, Global Clinical Development, provided however that (1) in the event that the matter relates solely to the Regeneron Compound, Regeneron shall have final decision-making authority and (2) in the

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event that the matter relates solely to the Replimune Compound, Replimune shall have final decision-making authority. "**Study Completion**" shall occur (i) for a randomized Study, on the fifth (5th) day after database lock of the Study results for such Study and (ii) for an open-label Study, when at least []* patients in such Study, or if Study enrollment is less than []* patients, the total enrolled patients in such Study, in each case have received []* of treatment under the Study.

3.10 Subject to (i) Regeneron's consent rights with respect to Replimune's use of Regeneron Compound Specific Clinical Data and Replimune's consent rights with respect to Regeneron's use of Replimune Compound Specific Clinical Data and (iii) Section 3.7, in the event that either Party seeks Regulatory Approval either (x) to change its respective Compound's label (where such Regulatory Approval has already been obtained), or (y) to obtain initial approval of its Compound or the Combination, in each case, based in whole or in part on the results of a Study, the Parties will reasonably cooperate in the preparation of the requisite filings with Regulatory Authorities, including the Responsible Party providing the Non-Responsible Party with any information related to such Study required for such Party's filing (e.g., investigator financial disclosures).

3.11 <u>Governance</u>. The Parties shall form a joint development team (the "Joint Development Committee" or "JDC"), made up of an equal number of representatives of Regeneron and Replimune (not to exceed three (3) each), which shall have responsibility for coordinating all clinical, regulatory, Compound supply and other activities under, and pursuant to, this Agreement. Each Party may invite a reasonable number of additional representatives to JDC meetings, provided that advance notice is provided. In addition, the JDC will have responsibility for reviewing and agreeing upon any proposed changes to the Clinical Obligations Schedule for a Study that may be proposed by either Party. If the JDC does not reach consensus on a proposed change to the Clinical Obligations Schedule for a Study, then the then-existing Clinical Obligations Schedule for such Study shall govern. For each Study, each Party shall designate a project manager (the "Project Manager") on the applicable Study Plan who shall be responsible for implementing and coordinating activities, and facilitating the exchange of information between the Parties, with respect to the applicable Study. The JDC shall meet as soon as practicable after the first Study Effective Date and then during such time as there is an ongoing Study, no less than once each Calendar Quarter, and more often as reasonably considered necessary at the request of either Party with reasonable notice, to provide an update on progress of each Study and make decisions regarding the conduct of each Study and any modifications to such Study's Protocol and Budget. Prior to any such meeting, each respective Project Manager shall provide an update in writing to the other Party's Project Manager, which update shall contain information about, as applicable, overall Study progress, recruitment status, ongoing data (if results are available), interim analysis (if results are available), final analysis and other information relevant to the conduct of the applicable Study. The JDC will attempt to reach decisions by consensus, except that Regeneron will determine in its sole discretion the dose and dosing regimen for the Regeneron Compound and Replimune will determine in its sole discretion the dose and dosing regimen for the Replimune Compound. The Parties hereby agree that changes to the responsibilities as set forth on the applicable Clinical Obligations Schedule require JDC consensus, and that changes to the Protocol may only be made in accordance with Section 4.1. When consensus is not achieved on any matter, the matter will be escalated to the

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Replimune Chief Medical Officer and the Regeneron Senior Vice President, Global Clinical Development, provided however that (1) in the event that the matter relates solely to the Regeneron Compound, Regeneron shall have final decision-making authority and (2) in the event that the matter relates solely to the Replimune Shall have final decision-making authority.

4. <u>Protocol and Related Documents</u>.

Unless otherwise agreed by the Parties as stated in the applicable Study Plan, the Protocol or Protocol synopsis and preliminary budget (as 41 applicable) for each Study that has been agreed to by the Parties as of the Study Effective Date for such Study shall be attached to each Study Plan for such Study. Notwithstanding the foregoing, the Parties intend to finalize such Protocol within []* (or such other time period as may be expressly stated in the applicable Study Plan) of the Study Effective Date, subject to the approval rights of each Party set forth in this Section 4.1; provided, that (a) if the Parties do not agree on a finalized Protocol within []* days (or such other time period as may be expressly stated in the applicable Study Plan) of the Study Effective Date, then either Party may, by written notice to the other Party, terminate the applicable Study Plan, it being understood that a lack of agreement on the final Protocol within such time periods shall not be a breach of this Agreement by either Party, and (b) such right to terminate due to failure to agree upon the final Protocol must be based on material changes to the Protocol or Protocol synopsis attached to the Study Plan and agreed to by the Parties as of the Study Effective Date for such Study required or requested by a Regulatory Authority. Notwithstanding the above, Regeneron will determine the dose and dosing regimen for the Regeneron Compound and will have the final decision on all matters relating specifically to the Regeneron Compound and any information regarding the Regeneron Compound included in the Protocol for each Study, and Replimune will determine the dose and dosing regimen for the Replimune Compound and will have the final decision on all matters relating specifically to the Replimune Compound and any information regarding the Replimune Compound included in the Protocol for each Study. Subject to the third sentence of Section 7.1 and Section 8.1, to the extent any changes need to be made to the mutually agreed Protocol, the Sponsoring Party shall have the final decision regarding the contents of such Protocol; provided that any material changes (other than relating solely to the Non-Sponsoring Party's Compound) to such Protocol, and any changes (whether or not material) relating to the Non-Sponsoring Party's Compound, shall require the Non-Sponsoring Party's prior written consent. The Non-Sponsoring Party will provide such consent, or a written explanation for why such consent is being withheld, within []* of receiving the Sponsoring Party's request therefor.

4.2 The Responsible Party shall prepare the patient informed consent form for the applicable Study in consultation with the other Party (it being understood that the portion of the informed consent form relating to the Other Party's Compound will be provided by such other Party). Any changes to such form that relate to the Other Party's Compound shall be subject to such other Party's written consent. The other Party will provide such consent, or a written explanation for why such consent is being withheld, within []* of receiving the Responsible Party's request therefore.

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4.3 *Financial Disclosure*. The Responsible Party, in working with the Other Party, shall be responsible for (a) tracking and collecting financial disclosure information from all "clinical investigators" involved in the Study and (b) preparing for submission by the Sponsor the certification and/or disclosure of the same in accordance with all Applicable Law, including, but not limited to, Part 54 of Title 21 of the United States Code of Federal Regulations (Financial Disclosure by Clinical Investigators) and related FDA Guidance Documents. The Responsible Party shall track and collect from all "clinical investigators" involved in the Study using one (1) "combined" certification and/or disclosure form for both Regeneron and Replimune. For purposes of this Section 4.3, the term "clinical investigators" shall have the meaning set forth in Part 54.2(d) of Title 21 of the United States Code of Federal Regulations.

4.4 <u>Transparency Reporting</u>. The Party making any payments and other transfers of value, including supply of Regeneron Compound and Replimune Compound, made to health care professionals, including, without limitation, investigators, steering committee members, data monitoring committee members, and consultants in connection with each Study in accordance with reporting requirements under Applicable Law, including, the Physician Payment Sunshine Act and state gift laws, and the European Federation of Pharmaceutical Industries and Associations Disclosure Code, and Replimune's and Regeneron's applicable policies, shall be solely responsible for reporting to the applicable Regulatory Authority such payments or transfers of value.

5. <u>Adverse Event Reporting</u>.

The Responsible Party will be solely responsible for compliance with all Applicable Law pertaining to safety reporting for the applicable Study and related activities. As soon as reasonably practical after the Study Effective Date (but in all cases prior to the first dosing of the first patient with a Product in a Study), the Parties will execute a new Pharmacovigilance Agreement or modify an existing Pharmacovigilance Agreement, as determined by the Sponsoring Party of the applicable Study to ensure the exchange of relevant safety data within appropriate timeframes and in appropriate format to enable the Parties to fulfill local and international regulatory reporting obligations and to facilitate appropriate safety reviews. The Pharmacovigilance Agreement will include safety data exchange procedures governing the coordination of collection, investigation, reporting, and exchange of information concerning any adverse experiences, pregnancy reports, and any other safety information arising from or related to the use of the Regeneron Compound and Replinune Compound in each Study, consistent with Applicable Law. Such guidelines and procedures shall be in accordance with, and enable the Parties and their Affiliates to fulfill local and international regulatory reporting obligations to Regulatory Authorities and the investigators. The Responsible Party will transmit to the other Party serious related life threatening or death events as set forth in the applicable Pharmacovigilance Agreement. The Responsible Party will be responsible for reporting all adverse events to the applicable Regulatory Authorities and the investigators. Execution of the Pharmacovigilance Agreement covering a Study is a prerequisite to the initiation of the Study.

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6.1 The term of this Agreement shall commence on the Effective Date and shall continue in full force and effect until terminated by either Party pursuant to this Article 6. The term of any Study Plan under this Agreement shall commence on the []* for such []* and shall continue in full force and effect until completion of the []* for the relevant Study or until earlier terminated by either Party pursuant to this Article 6.

6.2 In the event that the Non-Sponsoring Party reasonably believes that its Compound is being used in a Study in an unsafe manner and the Sponsoring Party fails to incorporate changes into the applicable Protocol reasonably requested by the Non-Sponsoring Party to address such issue, the Non-Sponsoring may immediately terminate the Study Plan covering such Study and the supply of its Compound for such Study upon written notice to the Sponsoring Party.

6.3 Either Party may terminate this Agreement or a Study Plan if the other Party commits a material breach of this Agreement or a material breach of its obligations under the particular Study Plan, as the case may be, and such material breach continues for []* after receipt of written notice thereof from the non-breaching Party specifying such material breach; provided that if such material breach cannot reasonably be cured within such []*, the breaching Party shall be given a reasonable period of time to cure such breach (not to exceed []* after receipt of notice).

6.4 Either Party may terminate this Agreement upon delivery of []* written notice to the other Party if (a) at the time of delivery of a Final Study Report, there is no other active Study Plan for which a Final Study Report has not been delivered, and (b) within []* after the delivery of the Final Study Report described in 6.4(a) above, the Parties have not entered into a Study Plan for another Study.

6.5 Either Party may terminate a Study Plan immediately upon written notice to the other party if the terminating Party determines in good faith, based on a review of the Clinical Data or other Study-related Know-How or information, that the Study performed pursuant to such Study Plan may unreasonably affect patient safety.

6.6 (a) Either Party may terminate a Study Plan immediately upon written notice to the other Party in the event that any Regulatory Authority takes any action, or raises any objection, that prevents the terminating Party from supplying its Compound for purposes of the Study performed pursuant to such Study Plan. (b) Additionally, either Party shall have the right to terminate this Agreement immediately (in whole or in part) upon written notice to the other Party in the event that it determines in its sole discretion to discontinue development of its Compound, for safety or legal reasons.

6.7 Each Party shall have the right to terminate this Agreement immediately upon any violation of Section 13.3 or any breach of a representation or warranty contained in Section 13.3 by the other Party. The non-terminating Party shall have no claim against the terminating Party for compensation for any loss of whatever nature by virtue of the termination of this Agreement in accordance with this Section 6.7. To the extent (and only to the extent) that the laws of the territory provide for any such compensation to be paid to the non-terminating Party upon the

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termination of this Agreement under this Section 6.7, the non-terminating Party hereby expressly agrees (to the extent possible under the laws of the territory) to waive or to repay to the Party terminating this Agreement any such compensation or indemnity.

6.8 In the event that an individual Study Plan is terminated, Replimune shall, at Regeneron's sole discretion, promptly either return or destroy all unused Regeneron Compound provided by Regeneron to be used in connection with the Study performed under such Study Plan, pursuant to Regeneron's instructions. If Regeneron requests that Replimune destroy the unused Regeneron Compound, Replimune shall provide written certification of such destruction. Likewise, Regeneron shall, at Replimune's sole discretion, promptly either return or destroy all unused Replimune Compound provided by Replimune to be used in connection with the Study performed under such Study Plan, pursuant to Replimune's instructions. If Replimune requests that Regeneron destroy the unused Replimune Compound, Regeneron shall provide written certification of such destruction. Notwithstanding the foregoing, the providing party may, in its sole discretion, permit the receiving party to reallocate unused Compound for other ongoing Studies being conducted under other Study Plans. In the event that this Agreement is terminated, Replimune shall, at Regeneron's sole discretion, promptly either return or destroy all unused Regeneron Compound pursuant to Regeneron's instructions. If Regeneron requests that Replimune destroy the unused Regeneron Compound, Regeneron shall, at Regeneron shall, at Regeneron compound, Regeneron compound pursuant to Regeneron's instructions. If Regeneron shall, at Regeneron destroy the unused Regeneron Compound, Regeneron compound, Regeneron shall provide written certification of such destruction. Likewise, Regeneron shall, at Regeneron d

6.9 The provisions of Sections 2.7, 3.5, 3.7, 3.8, 6.9 through 6.11, 9.1 through 9.3, 13.2, 13.4, 14.2 14.3 and Articles 1 (Definitions), 5 (Adverse Event Reporting) (solely as to adverse event reporting required for any SADRs/SAEs arising from a Study and occurring post-termination), 7 (Costs of Collaboration Program), 10 (Intellectual Property), 11 (Reprints; Rights of Cross-Reference), 12 (Publications), 15 (Use of Name), 18 (Assignment and Sub-Contracting), 20 (No Additional Obligations), 21 (Dispute Resolution and Jurisdiction), 22 (Notices), 23 (Relationship of the Parties) and 25 (Construction) shall survive the expiration or termination of this Agreement, in each case for such time period as may be expressly provided therefor.

6.10 Termination of this Agreement shall be without prejudice to any claim or right of action of either Party against the other Party for any prior breach of this Agreement.

6.11 Upon termination of this Agreement, each Party and its Affiliates shall promptly return to the other Party or destroy any Confidential Information of the other Party (other than Clinical Data and Inventions) furnished to the receiving Party by the other Party, except that the receiving Party shall have the right to retain one copy for record-keeping purposes.

7. <u>Costs of Collaboration Program</u>.

7.1 <u>Costs of Collaboration Program</u>. In addition to the preliminary budget attached to the Study Plan at the Study Effective Date pursuant to Section 4.1, unless otherwise specified in

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the applicable Study Plan, the final budget for each Study ("**Budget**") will be approved contemporaneously with the final Protocol in accordance with Section 4.1. Unless otherwise specified in the applicable Study Plan, Regeneron and Replimune will share equally the Development Costs of the Study as set forth in the applicable Budget. Any increase in the cost of a Study that exceeds the Budget by []* of the total cost of such Study as set forth in the Budget must be agreed upon in advance by the JDC. The Parties hereby acknowledge and agree that any material change to a Protocol may require an increase to the corresponding Budget. The Parties further agree that (i) Regeneron shall provide the Regeneron Compound for use in each Study, as described in Article 8 below; and (ii) Replimune shall provide the Replimune Compound for use in each Study, as described in Article 8 below.

7.2 Payment Terms. Within []* following the end of each calendar quarter during the Term and on a Study-by-Study basis, each Party (including any Affiliate) that has incurred any Development Costs in such calendar quarter in connection with the conduct of each Study hereunder shall deliver to the other Party a written report (each, a "**Development Costs Report**") setting forth in detail with supporting documentation the Development Costs incurred by such Party in such calendar quarter, by activity and in accordance with the applicable Budget. To the extent that the Development Costs Report shows that one Party has incurred and reported more Development Costs (that were included in the Budget for a particular Study or were otherwise approved in writing by the Parties) than the other Party with respect to the applicable calendar quarter (taking into account Prior Amounts), the Party incurring lesser Development Costs for such Study shall, within []* of receipt (or delivery, as applicable) of the other Party's Development Costs Report with appropriate supporting documentation and a corresponding invoice, pay to such other Party an amount equal to fifty percent (50%) of the excess Development Costs incurred by such other Party for the applicable calendar quarter for such Study (taking into account Prior Amounts) . All payments made by a Party to the other Party under this Agreement shall be made in U.S. Dollars via wire transfer to the accounts as set forth in the applicable Study Plan. For the purpose of calculating any sums due under, or otherwise reimbursable pursuant to, this Agreement, a Party shall convert any amount expressed in a foreign currency into U.S. Dollar equivalents using the average rate of exchange for the calendar quarter to which such payment relates using the arithmetic mean of the daily rate of exchange, as reported in Thomson Reuters Eikon as the "Mid Price Close", or using any other source as agreed to by the Parties.

7.3 <u>Records and Audit</u>.

7.3.1 Each Party shall, and shall cause its Affiliates to, keep complete books and records pertaining to Development Costs in sufficient detail to calculate all amounts payable hereunder. Each Party shall retain all such books and records for a period of at least three (3) years after the end of the period to which such books and records pertain, or for such longer period as may be required by Applicable Law.

7.3.2 At the request of a Party, the other Party shall permit an independent public accounting firm of nationally recognized standing designated by such auditing Party and

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reasonably acceptable to the other Party, at reasonable times during normal business hours and upon reasonable notice, to audit the books and records maintained pursuant to this Section 7.3 to ensure the accuracy of all reports and payments made hereunder; provided that the auditing Party shall cause such accounting firm to enter into a confidentiality agreement with the other Party in a form reasonably acceptable to such other Party obligating such firm to retain all such financial information in confidence pursuant to such confidentiality agreement. Such examinations may not (a) be conducted for any Calendar Quarter more than three (3) years after the end of such quarter, (b) be conducted more than once in any twelve (12) month period, or (c) be repeated for any Calendar Quarter. The accounting firm shall disclose to the auditing Party only whether the reports are correct and the specific details concerning any discrepancies. No other information shall be shared. Except as provided in Section 7.3.3, the cost of this audit shall be borne by the auditing Party, unless the audit reveals a variance of more than the greater of []* or []* from the reported amount, in which case the audited Party shall bear the cost of the audit. Subject to Section 7.3.3, no later than thirty (30) days after completion of the audit and reporting of the findings to the Parties, the audited Party shall pay the additional amounts, or the auditing Party shall reimburse the excess payments, as applicable.

7.3.3 In the event of a dispute with respect to any audit under Section 7.3.2, the Parties shall work in good faith to resolve the disagreement. If the Parties are unable to reach a mutually acceptable resolution of any such dispute within thirty (30) days, the dispute shall be submitted for resolution to a certified public accounting firm selected by the audited Party (subject to the approval of the auditing Party, such approval not to be unreasonably withheld, conditioned, or delayed) (the "Audit Arbitrator"); provided that the Parties shall cause the Audit Arbitrator to enter into a confidentiality agreement with the audited Party reasonably acceptable to the audited Party obligating such firm to retain all such financial information in confidence pursuant to such confidentiality agreement. The decision of the Audit Arbitrator shall be final and the costs of such arbitration as well as the initial audit shall be borne between the Parties in such manner as the Audit Arbitrator shall determine. Not later than []* after such decision and in accordance with such decision, the audited Party shall pay the additional amounts, or the auditing Party shall reimburse the excess payments, as applicable.

7.3.4 Upon the expiration of the []* period following the rendering of a Development Cost Report, such report shall be binding on the Parties, and each of the Parties and its Affiliates shall be released from any liability or accountability with respect to Development Costs for the period covered by such report.

7.4 <u>Taxes</u>. Replimune shall be liable for all income and other taxes (including interest) ("**Taxes**") imposed upon any payments made by Regeneron to Replimune under this Article 7, and likewise, Regeneron shall be liable for all Taxes imposed upon any payments made by Replimune to Regeneron under this Article 7. All payments made shall not be subject to withholding unless required by Applicable Law. If Applicable Law requires the withholding of Taxes, the payor shall make such withholding payments and shall subtract the amount thereof from the payments being made pursuant to this Agreement. The payor shall submit to the payee appropriate proof of payment of the withheld Taxes as well as the official receipts on a timely basis. Each Party agrees to reasonably cooperate with the other Party in claiming refunds or

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exemptions from such deductions or withholdings under any relevant agreement or treaty which is in effect.

8. <u>Supply and Use of the Compounds</u>.

8.1 <u>Supply of the Compounds</u>. Replimune and Regeneron will each use commercially reasonable efforts to supply, or cause to be supplied, the quantities of its respective Compound as are set forth on the applicable Study Plan, on the timelines set forth in the applicable Study Plan, in each case, for use in the applicable Study. In the event the Parties agree to amend a Protocol in such a manner that may affect the quantities of each Party's Compound to be provided, the Parties shall discuss in good faith the appropriate quantities of each Party's Compound to be provided consistent with such amended Protocol and shall within []* after such Protocol amendment update the applicable Study Plan to reflect the quantities of each Party's Compound to be provided and the schedule on which such quantities shall be provided consistent with such amended Protocol. If for any other reason either Party determines that the quantities of Compounds set forth on the applicable Study Plan are not sufficient to complete the applicable Study, such Party shall so notify the other Party, and the Parties shall discuss in good faith additional quantities of each Party's Compound to be provided and the schedule on which such quantities of such Study. Each Party shall also provide to the other Party a contact person for the supply of its Compound under each Study Plan. Notwithstanding the foregoing, or anything to the contrary herein, in the event that a Party is not supplying its Compound in accordance with the terms of a Study Plan or this Agreement then the other Party shall have no obligation to supply its Compound under such Study Plan or hereunder, and in the event that a Party is allocating supply of its Compound pursuant to Section 8.10, then the other Party may allocate proportionally.

8.2 <u>Minimum Shelf Life Requirements</u>. Each Party shall use commercially reasonable efforts to supply its Compound hereunder for each Study with sufficient shelf-life remaining at time of Delivery for its anticipated use in the relevant Study.

8.3 *Provision of Compounds*. The Responsible Party with respect to supply of Compounds to the Study sites will obtain such Compounds as set forth in this Section 8.3.

8.3.1 The Non-Responsible Party with respect to supply of Compounds to the Study sites for a particular Study will deliver the Non-Responsible Party's Compound DAP (INCOTERMS 2010) to the Responsible Party's, or its designee's, location as specified by the Responsible Party ("**Delivery**" with respect to such Non-Responsible Party's Compound). The Parties will discuss and align on a mutually agreed-to lead time for supply of the Non-Responsible Party's Compound. Risk of loss for the Non-Responsible Party's Compound shall transfer from the Non-Responsible Party to the Responsible Party at Delivery. The cost incurred by the Non-Responsible Party for supplying (including all Manufacturing, acceptance and release testing) the Non-Responsible Party's Compound to the Responsible Party shall not be deemed a Development Cost for purposes of Section 7.2. All costs associated with the subsequent transportation, warehousing and distribution of the Non-Responsible Party's Compound from the Responsible Party to clinical sites shall be a Development Cost in accordance with Section 7.2. The Responsible Party will: (i) take delivery of the Non-Responsible Party's Compound supplied

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hereunder; (ii) perform acceptance (including testing, if any) procedures allocated to it under the applicable Clinical Supply Quality Agreement; and promptly ship the Non-Responsible Party's Compound to the applicable Study sites, in compliance with cGMP, GCP and other Applicable Law and the applicable Clinical Supply Quality Agreement; and (iv) provide, from time to time at the reasonable request of the Non-Responsible Party, the following information: any applicable chain of custody forms, in-transport temperature recorder(s), records and receipt verification documentation, such other transport or storage documentation as may be reasonably requested by the Non-Responsible Party, and usage and inventory reconciliation documentation related to the Non-Responsible Party's Compound.

8.3.2 The Responsible Party is solely responsible, []*, for supplying (including all Manufacturing, packaging, labeling, acceptance and release testing) the Responsible Party's Compound for each Study in accordance with Section 8.1. The cost incurred by the Responsible Party for supplying (including all Manufacturing, acceptance and release testing) the Responsible Party's Compound []*. Further, the Responsible Party is solely responsible for the subsequent handling, storage, transportation, warehousing and distribution of the Responsible Party's Compound supplied hereunder from the Responsible Party to clinical sites, []*. The Responsible Party shall (i) release the Responsible Party's Compound and (ii) subsequently label and pack, and promptly ship, the Responsible Party's Compound to the applicable Study sites in compliance with cGMP, GCP and other Applicable Law and the applicable Clinical Supply Quality Agreement.

8.4 Labeling and Packaging; Use, Handling and Storage.

8.4.1 The Parties' obligations with respect to the labeling and packaging of the Compounds are as set forth in the applicable Clinical Supply Quality Agreement. The Non-Responsible Party with respect to supply of Compounds to the Study sites for a particular Study shall provide the Non-Responsible Party's Compound to the Responsible Party in packaged and labeled form for clinical use, and otherwise in accordance with all Applicable Law, including cGMP, GCP, and health, safety and environmental protections.

8.4.2 The Responsible Party shall (i) use the Non-Responsible Party's Compound supplied for a particular Study solely for purposes of shipment to the applicable Study sites for such Study; (ii) not use the Non-Responsible Party's Compound in any manner inconsistent with this Agreement or for any commercial purpose; and (iii) use, store, transport, handle and dispose of the Non-Responsible Party's Compound in compliance with Applicable Law and the applicable Clinical Supply Quality Agreement, as well as all reasonable instructions of the Non-Responsible Party. The Responsible Party shall not reverse engineer, reverse compile, disassemble or otherwise attempt to derive the composition or underlying information, structure or ideas of the Non-Responsible Party's Compound by physical, chemical or biochemical means except as necessary to perform its obligations under the applicable Clinical Supply Quality Agreement.

8.5 *Product Specifications.* A certificate of analysis shall accompany each shipment of the Non-Responsible Party's Compound to the Responsible Party. The Responsible Party shall

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be responsible for any failure of the Non-Responsible Party's Compound to meet the Specifications to the extent caused by shipping, storage or handling conditions after Delivery to the Responsible Party hereunder.

8.6 *Changes to Manufacturing.* Each Party may make changes from time to time to its Compound or the Manufacturing Site without notice to the other Party; provided that such changes shall be in accordance with the applicable Clinical Supply Quality Agreement.

8.7 <u>Product Testing; Noncompliance</u>.

8.7.1 *After Manufacturer's Release.* After Manufacturer's Release of the Non-Responsible Party's Compound and concurrent with shipment to the Responsible Party, the Non-Responsible Party shall provide the Responsible Party with such certificates and documentation as are described in the applicable Clinical Supply Quality Agreement, which documentation will support release of the Non-Responsible Party's Compound for human use ("**Disposition Package**"). The Responsible Party shall, upon receipt of the Non-Responsible Party's Compound and within the time defined in the applicable Clinical Supply Quality Agreement, perform with respect to the Non-Responsible Party's Compound, the acceptance (including testing, if any) procedures allocated to it under the applicable Clinical Supply Quality Agreement. As described in the Clinical Supply Quality Agreement, the Responsible Party shall be solely responsible for taking all steps necessary to determine that the Responsible Party's Compound and the Non-Responsible Party's Compound, as applicable, are suitable for release before making such Responsible Party's Compound or Non-Responsible Party's Compound, as applicable, are suitable for release before making such Responsible for storage and maintenance of the Non-Responsible Party's Compound until it is shipped to the Study sites, which storage and maintenance shall be in compliance with (a) the Specifications for the Non-Responsible Party's Compound, the applicable Clinical Supply Quality Agreement and Applicable Law, and (b) any specific storage and maintenance requirements as may be provided by the Non-Responsible Party from time to time.

8.7.2 Non-Conformance.

(a) In the event that the Responsible Party becomes aware that the Non-Responsible Party's Compound may have a Non-Conformance, despite testing and quality assurance activities (including any activities conducted by the Parties under Sections 8.7.1), the Responsible Party shall immediately notify the Non-Responsible Party in accordance with the procedures of the applicable Clinical Supply Quality Agreement. The Parties shall investigate any Non-Conformance in accordance with Section 8.9 and any discrepancy between them shall be resolved in accordance with Section 8.8.

(b) In the event that any proposed or actual shipment of the Non-Responsible Party's Compound (or portion thereof) shall be agreed to have a Non-Conformance at the time of Delivery to the Responsible Party, then unless otherwise agreed to by the Parties, the Non-Responsible Party shall replace, using diligent efforts, such Non-Responsible Party's Compound as is found to have a Non-Conformance (with respect to the Non-Responsible Party's Compound that has not yet been administered in the course of performing the applicable Study). Unless

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otherwise agreed to by the Parties in writing, the sole and exclusive remedies of the Responsible Party with respect to any Non-Responsible Party's Compound that is found to have a Non-Conformance at the time of Delivery shall be (i) replacement of such Non-Responsible Party's Compound as set forth in this Section 8.7.2(b), (ii) indemnification under Section 14.2 (to the extent applicable) and (iii) termination of the applicable Study Plan covering the Study for which the shipment was made pursuant to Section 6.3 (to the extent applicable, but subject to the applicable cure periods set forth therein); provided that, for clarity, the Responsible Party shall not be deemed to be waiving any rights under Section 8.16. In the event the Non-Responsible Party's Compound is lost or damaged by the Responsible Party after Delivery, the Non-Responsible Party shall provide additional amounts of the Non-Responsible Party for its fully-burdened manufacturing costs of such replaced Non-Responsible Party's Compound. Except as set forth in the foregoing sentence, the Non-Responsible Party shall have no obligation to replace the Non-Responsible Party's Compound with any amounts of the Non-Responsible Party's Compound other than the amounts of such Non-Responsible Party's Compound as has been agreed or determined to have a Non-Conformance at the time of Delivery to the Responsible Party.

(c) The Responsible Party shall be responsible for, and the Non-Responsible Party shall have no obligations or liability with respect to, any amounts of the Responsible Party's Compound supplied hereunder that is found to have a Non-Conformance. The Responsible Party shall replace, using diligent efforts, any of the Responsible Party's Compound as is found to have a Non-Conformance (with respect to the Responsible Party's Compound that has not yet been administered in the course of performing the applicable Study). Unless otherwise agreed to by the Parties in writing, the sole and exclusive remedies of the Non-Responsible Party with respect to any amounts of the Responsible Party's Compound that is found to have a Non-Conformance at the time of Delivery shall be (i) replacement of such amounts of the Responsible Party's Compound as set forth in this Section 8.7.2(c), (ii) indemnification under Section 14.2 (to the extent applicable) and (iii) termination of the applicable Study Plan covering the Study for which the shipment was made pursuant to Section 6.3 (to the extent applicable, but subject to the applicable cure periods set forth therein); provided that, for clarity, the Non-Responsible Party shall not be deemed to be waiving any rights under Section 8.16.

8.8 <u>Resolution of Discrepancies</u>. If the Non-Responsible Party disagrees with any determination of Non-Conformance of the Non-Responsible Party's Compound by the Responsible Party, such discrepancy shall be escalated to the head of quality of each Party (or such person's designee) for resolution.

8.9 *Investigations*. The process for investigations of any Non-Conformance shall be handled in accordance with the provisions set forth in the applicable Clinical Supply Quality Agreement.

8.10 <u>Shortage; Allocation</u>. Without limiting Section 8.1, in the event of a shortage of a Compound such that a Party reasonably believes that it will not be able to fulfill its supply obligations hereunder with respect to its Compound, such Party will provide prompt written notice to the other Party thereof (including the quantity of its Compound that such Party

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reasonably determines it will be able to supply) and, upon request, the Parties will promptly discuss such situation (including how the quantities of Compound that such Party is able to supply hereunder will be allocated within the applicable Study, or among any ongoing Studies). Notwithstanding anything to the contrary contained herein, in the event of a shortage of a Party's Compound, the Party experiencing such shortage shall have sole discretion, subject to Applicable Law, to determine the quantity of Compound that it will be able to supply as a result of such shortage, and such Party shall not be deemed to be in breach of this Agreement for failure to supply quantities of such Party's Compound hereunder as a result of such shortage. In case of one Party's shortage of its Compound, the other Party shall be relieved of its obligations under this Agreement as they directly relate to the shortage.

8.11 <u>Regulatory Responsibility</u>. The responsibilities of the Parties with respect to communication and filings with Regulatory Authorities related to the Compounds supplied hereunder in connection with the applicable Study will be as set forth in the Pharmacovigilance Agreement and the applicable Clinical Supply Quality Agreement entered into by the Parties or their Affiliates in connection herewith, except that the Non-Responsible Party will separately submit any CMC information with respect to the Non-Responsible Party's Compound directly to any Regulatory Authorities, or delegate such responsibility to the Responsible Party, as may be necessary.

8.12 <u>Records; Audit Rights</u>. The Responsible Party will keep complete and accurate records pertaining to its use and disposition of the Non-Responsible Party's Compound (including its storage, shipping (cold chain) and chain of custody activities) and, upon reasonable request of the Non-Responsible Party, will make such records open to review by the Non-Responsible Party for the purpose of conducting investigations for the determination of the safety and/or efficacy of the Non-Responsible Party's Compound and the Responsible Party's compliance with this Agreement with respect to the Non-Responsible Party's Compound.

8.13 *Quality*. Quality matters related to the Manufacture and supply of the Compounds shall be governed by the terms of the applicable Clinical Supply Quality Agreement in addition to the relevant quality terms of this Agreement. As soon as reasonably practical after the Study Effective Date (but in all cases before the first shipment of Product to a Party hereunder), the Parties shall enter into the Clinical Supply Quality Agreement with respect to the supply of Product to be supplied to the other Party hereunder.

8.14 *Quality Control*. Each Party shall implement and perform operating procedures and controls for sampling, stability and other testing of its Compound, and for validation, documentation and release of its Compound and such other quality assurance and quality control procedures as are required by the Specifications, cGMPs and the applicable Clinical Supply Quality Agreement.

8.15 *Audits and Inspections*. The Parties' audit and inspection rights are governed by the terms of the applicable Clinical Supply Quality Agreement.

8.16 <u>Recalls</u>. Recalls of the Compounds shall be governed by the terms of the applicable Clinical Supply Quality Agreement.

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9. <u>Confidentiality</u>.

9.1 Obligations of Non-Use and Non-Disclosure.

9.1.1 Replimune and Regeneron agree to hold in confidence any Confidential Information provided by the other Party, and neither Party shall use Confidential Information of the other Party except to fulfill such Party's obligations under this Agreement. Without limiting the foregoing, Regeneron may not use Confidential Information disclosed by or on behalf of Replimune relating to the []*. Replimune may not use Confidential Information disclosed by or on behalf of Regeneron relating to the []* other than for purposes of each Study.

9.1.2 Neither Party shall, without the prior written permission of the other Party, disclose any Confidential Information of the other Party to any Third Party except to the extent disclosure (i) is required by Applicable Law, including any securities laws or regulations; (ii) is pursuant to the terms of this Agreement; or (iii) is necessary for the conduct of each Study, and in each case ((i) through (iii)) provided that the disclosing Party shall provide reasonable advance notice to the other Party before making such disclosure and further provided that the recipient of such Confidential Information shall be bound by an obligation of confidentiality at least as stringent as the obligations contained herein, except where otherwise provided in Section 9.1.3. For the avoidance of doubt, the Responsible Party may, without the other Party's consent, disclose the other Party's Confidential Information to clinical trial sites and clinical trial investigators performing the applicable Study, vendors that provide clinical trial services, the data safety monitoring and advisory board relating to the applicable Study, and regulatory agencies such as the FDA, EMA or other Regulatory Authorities working with the Responsible Party on the applicable Study, in each case to the extent necessary for the performance of the applicable Study and provided that such persons (other than governmental entities) are bound by an obligation of confidentiality at least as stringent as the obligations contained herein for a period of at least five (5) years.

9.1.3 Notwithstanding the foregoing, Regeneron may share Confidential Information of Replimune with []* in connection with the development and commercialization of the Regeneron Compound under Regeneron's collaboration with []*. In addition, and notwithstanding the foregoing clauses of this Section 9.1, each Party may disclose Confidential Information belonging to the other Party to the extent such disclosure is reasonably necessary in the following instances:

- (a) prosecuting or defending litigation;
- (b) complying with the rules or regulations of any securities exchange on which such Party's stock is listed; and

(c) (A) in communications with actual and/or bona fide []* under confidentiality provisions as least as protective of Confidential Information as those of this Agreement; provided such disclosure shall be limited to the []*; provided that (i) neither Party may disclose []* in violation of the exclusivity restrictions on Competitive Studies as set forth in Section 2.7 and (ii) Regeneron may not disclose []* and Replimune may not disclose []*, in each

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case with respect to a []* Study, in the case where Sponsoring Party is in compliance with respect to its obligations under Section 12.2 but the data from the Study has not yet been published or publicly presented, unless the other Party has had an opportunity to review and approve the contents of such disclosure, such approval not to be unreasonably withheld, it being understood that no such consent may not be withheld for the disclosure []* from such Study, and (B) in communications with actual and/or bona fide potential investors (including firewalled strategic investors) under confidentiality provisions as least as protective of Confidential Information as those of this Agreement; provided that, such disclosure shall be limited to Clinical Data and such confidentiality obligations shall extend for such time periods as are common in the industry, but in no event for less than twelve (12) months. []*

Notwithstanding the foregoing, if a Party is required or otherwise intends to make a disclosure of any other Party's Confidential Information 9.2 pursuant to this Section 9.1.3(a), it shall give []* advance notice to such other Party of such impending disclosure and, in the case of disclosures under clause (a), endeavor in good faith to secure confidential treatment of such Confidential Information and/or reasonably assist the Party that owns such Confidential Information in seeking a protective order or other confidential treatment. If a Party is required by Applicable Law to disclose Confidential Information that is subject to 9.1.3(b), such Party shall, to the extent permitted by Applicable Law, []* inform the other Party of the disclosure that is being sought in order to provide the other Party an opportunity to challenge or limit the disclosure obligations and such Party shall disclose only that portion of the Confidential Information it is required to disclose by Applicable Law. The Party required by Applicable Law to disclose the other Party's Confidential Information shall cooperate with the other Party, at the other Party's expense, in any attempt the other Party may make to obtain a protective order for its Confidential Information. If either Party concludes that a copy of this Agreement must be filed with the United States Securities and Exchange Commission or similar regulatory agency in a country other than the United States, such Party will provide the other Party with a copy of this Agreement showing any provisions hereof as to which the Party proposes to request confidential treatment, will provide the other Party with an opportunity to comment on any such proposed redactions and to suggest additional redactions, and will take such Party's reasonable and timely comments into consideration before filing the Agreement. Notwithstanding the foregoing Sections 9.1.1 and 9.1.2, (i) Inventions that constitute Confidential Information and are jointly owned by the Parties shall constitute the Confidential Information of both Parties and each Party shall have the right to use such Confidential Information consistent with Articles 10, 11 and 12 and (ii) Inventions that constitute Confidential Information and are solely owned by one Party shall constitute the Confidential Information of that Party and each Party shall have the right to use such Confidential Information consistent with Articles 10, 11 and 12.

9.3 All Confidential Information containing personal identifiable data shall be handled in accordance with all data protection and privacy laws, rules and regulations applicable to such Party.

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10. Intellectual Property.

10.1 Joint Ownership and Prosecution.

10.1.1 Subject to the provisions of Sections 10.2 and 10.3, all rights to all Inventions relating to the Combination or improvements thereto (each a "**Jointly Owned Invention**"), and all Know-How that (i) is generated by either or both of the Parties in the course of the conduct of its activities under this Agreement, and (ii) is not a Jointly Owned Invention ("**Collaboration Know-How**"), shall be owned jointly by Replimune and Regeneron, and each Party hereby assigns to the other a joint ownership interest in all such Jointly Owned Inventions and Collaboration Know-How. Replimune and Regeneron shall each be entitled to use the Jointly Owned Inventions and Collaboration Know-How without accounting or financial payment to the other Party and without the consent of the other Party. For those countries where a specific license is required for a joint owner of a Jointly Owned Invention or Collaboration Know-How to practice such Jointly Owned Invention or Collaboration Know-How in such countries, or to sublicense its rights thereunder (i) Regeneron hereby grants to Replimune a perpetual, irrevocable, non-exclusive, worldwide, royalty-free, fully paid-up license, transferable and sublicensable, under Regeneron's right, title and interest in and to all Jointly Owned Inventions and Collaboration Know-How to use such Inventions in accordance with the terms and conditions of this Agreement (including subject to Section 2.7) and (ii) Replimune hereby grants to Regeneron a perpetual, irrevocable, non-exclusive, under Replimune's right, title and interest in and to all Jointly Owned Inventions in accordance with the terms and Collaboration Know-How to use such Inventions in accordance with the terms and Collaboration Know-How to use such Inventions in accordance with the terms and conditions of this Agreement. For clarity, the terms of this Agreement do not provide Replimune or Regeneron with any rights, title or interest or any license to the other Party's background intellectual property except as necessary to conduct the

10.1.2 Promptly following the Effective Date, patent representatives of each of the Parties shall meet (in person or by telephone) to discuss the patenting strategy for any Jointly Owned Inventions that may arise. In particular, the Parties shall discuss which Party will file a patent application (including any provisional, substitution, divisional, continuation, continuation in part, reissue, renewal, reexamination, extension, supplementary protection certificate and the like) in respect of any Jointly Owned Invention (each, a "Joint Patent Application") and whether the Parties wish to appoint joint patent counsel. In any event, the Parties shall consult and reasonably cooperate with one another in, and shall equally share the expenses for, the preparation, filing, prosecution (including prosecution strategy) and maintenance of Joint Patent Applications and Joint Patents, including defense of any invalidity challenges thereto. In the event that one Party (the "Filing Party") wishes to file a patent application for a Jointly Owned Invention and the other Party (the "Non-filing Party") does not want to file any patent application for such Jointly Owned Invention or does not want to file in a particular country,

the Non-filing Party shall execute such documents and perform such acts at the Filing Party's expense as may be reasonably necessary to effect an assignment of such Jointly Owned Invention to the Filing Party (in such country or all countries, as applicable) in a timely manner to allow the Filing Party to prosecute such patent application. Likewise, if a Party (the "**Opting-out Party**") wishes to discontinue the prosecution and maintenance of a Joint Patent Application, the other Party, at its sole option (the "**Continuing Party**"), may continue such prosecution and maintenance. In such event, the Opting-out Party shall execute such documents and perform such acts at the Continuing Party's expense as may be reasonably necessary to effect an assignment of such Joint Patent Application to the Continuing Party (in such country or all countries, as applicable) in a timely manner to allow the Continuing Party to prosecute and maintain such patent application. Any Joint Patent Application

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or Jointly Owned Invention so assigned shall thereafter be owned solely by the Continuing Party or Filing Party (as applicable), and the Opting-out Party or Non-filing Party (as applicable) (i) to the extent in the United States, the European Union, the United Kingdom or Japan, the Opting-out Party or Non-filing Party (as applicable) shall have no right to practice under such Joint Patent Application or any patent claiming such Jointly Owned Invention in the applicable country or countries and, for the avoidance of doubt, any such patent, when issued, shall not be a Joint Patent and (ii) to the extent not in the United States, the European Union, the United Kingdom or Japan, the Opting-out Party or Non-filing Party (as applicable) shall have []*.

10.1.3 Except as expressly provided in Section 10.1.2, each Party agrees to make no patent application based on the other Party's Confidential Information, and to give no assistance to any Third Party for such application, without the other Party's prior written authorization.

10.1.4 Each Party shall promptly provide the other Party with written notice reasonably detailing any known or alleged infringement or misappropriation by a Third Party of Joint Patents, as well as any declaratory judgment or similar actions alleging the invalidity, unenforceability or noninfringement of Joint Patents. Replimune shall have the first right to initiate legal action to enforce all Joint Patents against infringement or misappropriation by any Third Party that is manufacturing, developing, marketing, or seeking to market, an Oncolytic Virus, or to defend any declaratory judgment action relating thereto, at its sole expense. In the event such course of action includes litigation, Regeneron may choose, at its own expense, to be represented in such action by counsel of its own choice. If Regeneron is required as a necessary party to such action, each Party shall pay their respective expenses associated therewith. In the event that Replimune fails to initiate or defend such action, Regeneron shall not have any right to do so without consent of Replimune. Each Party shall keep the other Party reasonably informed as to any legal or commercial courses of action it pursues pursuant to this subsection. Regeneron shall have the first right to initiate legal action to enforce all Joint Patents against infringement or misappropriation by any Third Party that is manufacturing, developing, marketing, or seeking to market, a PD-1 Antagonist, or to defend any declaratory judgment action relating thereto, at its sole expense. In the event such course of action includes litigation, Replimune may choose, at its own expense, to be represented in such action by counsel of its own choice. If Replimune is required as a necessary party to such action, each Party shall pay their respective expenses associated therewith. In the event that Regeneron fails to initiate or defend such action, Replimune shall not have any right to do so without consent of Regeneron. Each Party shall keep the other Party reasonably informed as to any legal or commercial courses of action it pursues pursuant to this subsection. In connection with any proceeding, neither Party shall enter into any settlement without the prior written consent of the other Party. Neither Party shall have the first right to initiate legal action to enforce all Joint Patents against infringement or misappropriation by any Third Party that is manufacturing, developing, marketing, or seeking to market, the Combination, or to defend any declaratory judgment action relating thereto, at its sole expense, and the Parties shall not proceed in any such action unless and until they agree on which Party shall be the initiating Party in any such action.

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10.1.5 If one Party brings any prosecution or enforcement action or proceeding against a Third Party with respect to any Joint Patent, the second Party agrees to be joined as a party plaintiff where necessary and to give the first Party reasonable assistance and authority to file and prosecute the suit, at the first Party's expense. The costs and expenses of the Party bringing suit under this Section 10.1.5 shall be borne by such Party, and any damages or other monetary awards recovered shall be shared as follows, unless otherwise agreed by the Parties: (i) the amount of such recovery actually received by the Party controlling such action shall be first applied proportionately to the out-of-pocket costs of each Party in connection with such action; and then (ii) any remaining proceeds shall be divided evenly between Replimune and Regeneron. A settlement or consent judgment or other voluntary final disposition of a suit under this Section 10.1.5 may not be entered into without the consent of the Party not bringing the suit.

10.2 <u>Inventions Owned by Replimune</u>. Notwithstanding Section 10.1, the Parties agree that all rights to (a) all Inventions relating solely to the Replimune Compound (regardless of inventorship) and (b) all Know-How (as distinct from Clinical Data which is covered by Section 3.7) that is generated (by either or both Parties) in the course of the conduct of its activities under this Agreement and relating solely to the Replimune Compound, in each case, are the exclusive property of Replimune, and Regeneron hereby assigns any rights therein to Replimune. Replimune shall be entitled to file in its own name relevant patent applications and to own resultant patent rights for any such Invention.

10.3 <u>Inventions Owned by Regeneron</u>. Notwithstanding Section 10.1, the Parties agree that all rights to (a) all Inventions relating solely to the Regeneron Compound (regardless of inventorship) and (b) all Know-How (as distinct from Clinical Data which is covered by Section 3.7) that is generated (by either or both Parties) in the course of the conduct of its activities under this Agreement and relating solely to the Regeneron Compound, in each case, are the exclusive property of Regeneron, and Replimune hereby assigns any rights therein to Regeneron. Regeneron shall be entitled to file in its own name relevant patent applications and to own resultant patent rights for any such Invention.

11. <u>Reprints; Rights of Cross-Reference</u>.

Consistent with applicable copyright and other laws, each Party may use, refer to, and disseminate reprints of scientific, medical and other published articles and materials from journals, conferences and/or symposia relating to each Study which disclose the name of the other Party, provided such use does not constitute an endorsement of any commercial product or service by the other Party.

12. Publications.

12.1 The Sponsoring Party will register each Study with the Clinical Trials Registry located at www.clinicaltrials.gov no sooner than one (1) week prior to the date of First Site Ready for such Study (the "**First Site Ready Date**"), and no later than the First Site Ready Date, except to the extent required otherwise by Applicable Law. The Sponsoring Party is committed to timely publication of the results following Study Completion for a Study, after the Parties (or relevant Party) have taken appropriate action to secure intellectual property rights (if any) arising

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from such Study. Authorship of publications of the Clinical Data for a Study will be determined in accordance with appropriate scientific and academic standards and customs. Proper acknowledgement will be made for the contributions of each Party to the Clinical Data for each Study.

12.2 The Sponsoring Party shall use reasonable efforts to publish or present scientific papers dealing with each Study in accordance with accepted scientific practice and its internal policies and procedures.

12.3 The Parties agree that prior to submission of the results of each Study for publication or presentation or any other dissemination of results including oral dissemination, the publishing Party shall invite the other to comment on the content of the material to be published or presented according to the following procedure:

(i) At least []* prior to submission for publication of any paper, letter or any other publication, or []* prior to submission for presentation of any abstract, poster, talk or any other presentation, the publishing Party shall provide to the other Party the full details of the proposed publication or presentation in an electronic version (cd-rom or email attachment). Upon written request from the other Party, the publishing Party agrees not to submit data for publication/presentation for []* in order to allow for actions to be taken to preserve rights for patent protection.

(ii) The publishing Party shall give reasonable consideration to any request by the other Party made at least []* prior to the running of the periods mentioned in clause (i) above to modify the publication.

(iii) The publishing Party shall remove all Confidential Information of the other Party as requested by the other Party before finalizing the publication.

12.4 Neither Party shall publish, for any purpose, the results of the applicable Study without the prior written approval of the other Party, which approval shall be obtained in accordance with the procedure set forth in Section 12.3 (i) through (iii) and shall not be unreasonably delayed, conditioned or withheld.

12.5 Except as required by judicial order or Applicable Law, neither Party shall make any public announcement concerning this Agreement or any Study Plan without the prior written consent of the other Party. The Party preparing any such public announcement pursuant to the previous sentence shall provide the other Party with a draft thereof at least []* prior to the date on which such Party would like to make the public announcement. Notwithstanding the foregoing, the Parties may issue a joint press release announcing the execution of this Agreement and the associated Study Plan executed concurrently with this Agreement. Each Party agrees to identify the other Party and acknowledge its support in any press release and any other publication or presentation of the results of the applicable Study.

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13. <u>Representations and Warranties; Disclaimers</u>.

13.1 Each of Replimune and Regeneron represents and warrants to the other that it has the full right and authority to enter into this Agreement and to perform its obligations hereunder, that it is authorized by any necessary corporate action to enter into this Agreement and that it has no impediment to enter into the transaction contemplated in this Agreement.

13.2 Neither Party undertakes that any Study shall lead to any particular result, nor is the success of a Study guaranteed. Neither Party accepts any responsibility for any use that the other Party may make of any Clinical Data nor for advice or information given in connection therewith.

13.3 Anti-Corruption.

13.3.1 In performing their respective obligations hereunder, the Parties acknowledge that the corporate policies of Replimune and Regeneron and their respective Affiliates require that each Party's business be conducted within the letter and spirit of the law. By signing this Agreement, each Party agrees to conduct the business contemplated herein in a manner that is consistent with all Applicable Law, including the U.S. Foreign Corrupt Practices Act, good business ethics, and its ethics and other corporate policies.

13.3.2 Each Party shall not contact, or otherwise knowingly meet with, any Government Official for the purpose of discussing activities arising out of or in connection with this Agreement, without the prior written approval of the other Party, except where such meeting is consistent with the purpose and terms of this Agreement and in compliance with Applicable Law.

13.3.3 Each Party represents that shall not employ or subcontract with any person or entity that is excluded, debarred, suspended or otherwise ineligible for government programs in the course of performing activities under this Agreement.

13.3.4 Each Party represents that it is not excluded, debarred, suspended, proposed for suspension or debarment, or otherwise ineligible for government programs.

13.4 EXCEPT AS EXPRESSLY PROVIDED HEREIN, REGENERON MAKES NO WARRANTIES, EXPRESS OR IMPLIED, INCLUDING ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, WITH RESPECT TO THE REGENERON COMPOUND, AND REPLIMUNE MAKES NO WARRANTIES, EXPRESS OR IMPLIED, INCLUDING ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, WITH RESPECT TO THE REPLIMUNE COMPOUND. Replimune assumes no responsibility and shall have no liability for the nature, conduct or results of any research, testing or other work hereunder. Regeneron assumes no responsibility and shall have no liability for the nature, conduct or results of any research, testing or other work performed by or on behalf of Replimune hereunder

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14. Insurance; Indemnification; Limitation of Liability.

14.1 <u>Insurance</u>. Each Party warrants that it maintains a policy or program of insurance or self-insurance at levels sufficient to support the indemnification obligations assumed herein. Specifically with regards to clinical trials, whichever party is designated as the Sponsor for the clinical trial, that party will be responsible to procure Products & Clinical Trial Liability insurance with an insurer that has an A.M. Best rating of at least A- VII that is valid for each country/geography that the trial is being conducted in and will name the other party as additional insured on the insurance policy. Upon written request, a Party shall provide evidence of such insurance.

14.2 Indemnification.

14.2.1 *Indemnification by Replimune*. Replimune agrees to defend, indemnify and hold harmless Regeneron, its Affiliates, and its and their employees, directors, subcontractors and agents from and against any loss, damage, reasonable costs and expenses (including reasonable attorneys' fees and expenses) incurred in connection with any claim, proceeding, or investigation by a Third Party arising out of this Agreement or any Study (a "**Liability**"), to the extent that such Liability (A) was directly caused by (i) negligence or willful misconduct on the part of Replimune (or any of its Affiliates, or its or their employees, directors, subcontractors or agents); (ii) a breach on the part of Replimune of any of its representations and warranties or any other covenants or obligations of Replimune (or any of its Affiliates, or its or their employees, directors, subcontractors or agents) under this Agreement or any Study Plan; or (iii) a breach of Applicable Law by Replimune, or (B) is determined to be attributable solely to the Replimune Compound and not the Combination.

14.2.2 *Indemnification by Regeneron.* Regeneron agrees to defend, indemnify and hold harmless Replimune, its Affiliates, and its and their employees, directors, subcontractors and agents from and against any Liability to the extent such Liability (A) was directly caused by (i) negligence or willful misconduct on the part of Regeneron (or any of its Affiliates, or its and their employees, directors, subcontractors or agents); (ii) a breach on the part of Regeneron of any of its representations and warranties or any other covenants or obligations of Regeneron (or any of its Affiliates, or its or their employees, directors, subcontractors or agents) under this Agreement or any Study Plan; or (iii) a breach of Applicable Law by Regeneron; or (B) is determined to be attributable solely to the Regeneron Compound and not the Combination.

14.2.3 *Other Liability.* Any Liability that is not indemnifiable under either Section 14.2.1 or 14.2.2 shall be shared equally by the Parties.

14.2.4 *Procedure.* The obligations of Regeneron and Replimune under this Section 14.2 are conditioned upon the delivery of written notice to Regeneron or Replimune, as the case might be, of any potential Liability within a reasonable time after the indemnified Party becomes aware of such potential Liability. The indemnifying Party will have the right to assume the defense of any suit or claim related to the Liability if it has assumed responsibility for the suit or claim in writing. The indemnified Party may participate in (but not control) the defense thereof at its sole cost and expense.

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14.2.5 *Study Subjects.* Neither Party shall offer compensation on behalf of the other Party to any Study subject or bind the other Party to any indemnification obligations in favor of any Study subject without the express written consent of such other Party.

14.3 <u>LIMITATION OF LIABILITY</u>. OTHER THAN WITH RESPECT TO THE OBLIGATIONS OF EACH PARTY UNDER SECTION 2.7 AND ARTICLE 9, IN NO EVENT SHALL EITHER PARTY (OR ANY OF ITS AFFILIATES OR SUBCONTRACTORS) BE LIABLE TO THE OTHER PARTY FOR, NOR SHALL ANY INDEMNIFIED PARTY HAVE THE RIGHT TO RECOVER, EXCEPT AS PROVIDED BELOW, ANY SPECIAL, INDIRECT, INCIDENTAL, PUNITIVE OR CONSEQUENTIAL DAMAGES (INCLUDING LOST PROFITS OR DAMAGES FOR LOST OPPORTUNITIES), WHETHER IN CONTRACT, WARRANTY, NEGLIGENCE, TORT, STRICT LIABILITY OR OTHERWISE, ARISING OUT OF (x) THE MANUFACTURE OR USE OF ANY COMPOUND SUPPLIED HEREUNDER OR (y) ANY BREACH OF OR FAILURE TO PERFORM ANY OF THE PROVISIONS OF THIS AGREEMENT OR ANY REPRESENTATION, WARRANTY OR COVENANT CONTAINED IN OR MADE PURSUANT TO THIS AGREEMENT, EXCEPT THAT SUCH LIMITATION SHALL NOT APPLY TO ANY LIABILITY FOR DAMAGES PAID OR PAYABLE TO A THIRD PARTY BY AN INDEMNIFYING PARTY HEREUNDER.

15. <u>Use of Name.</u>

Except as otherwise provided herein, neither Party shall have any right, express or implied, to use in any manner the name or other designation of the other Party or any other trade name, trademark or logo of the other Party for any purpose in connection with the performance of this Agreement.

16. Force Majeure.

If in the performance of this Agreement, one of the Parties is prevented, hindered or delayed by reason of any cause beyond such Party's reasonable control (*e.g.*, war, riots, fire, strike, governmental laws), such Party shall be excused from performance to the extent that it is necessarily prevented, hindered or delayed (**"Force Majeure"**). The non-performing Party will notify the other Party of such Force Majeure within ten (10) days after such occurrence by giving written notice to the other Party stating the nature of the event, its anticipated duration, and any action being taken to avoid or minimize its effect. The suspension of performance will be of no greater scope and no longer duration than is necessary and the non-performing Party will use commercially reasonable efforts to remedy its inability to perform.

17. Entire Agreement; Modification.

The Parties agree to the full and complete performance of the mutual covenants contained in this Agreement. This Agreement, together with the Clinical Supply Quality Agreement(s), the Pharmacovigilance Agreement and any Study Plan, constitutes the sole, full and complete agreement by and between the Parties with respect to the subject matter of this Agreement, and all prior agreements, understandings, promises and representations, whether written or oral, with respect thereto are superseded by this Agreement. No amendments, changes, additions, deletions

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or modifications to or of this Agreement shall be valid unless reduced to writing and signed by the Parties hereto.

18. Assignment.

Neither Party shall assign or transfer this Agreement or any Study Plan without the prior written consent of the other Party, which consent shall not be unreasonably withheld; provided, however, that either Party may assign this Agreement or any Study Plan, in whole or in part, to one or more of its Affiliates without the other Party's consent, and any and all rights and obligations of either Party may be exercised or performed by its Affiliates, provided that such Affiliates agree to be bound by this Agreement. Notwithstanding the foregoing, Regeneron may, without Replimune's consent, assign this Agreement and the Study Plans and its rights and obligations hereunder in connection with a Change of Control of Regeneron and Replimune may, without Regeneron's consent, assign this Agreement and the Study Plans and its rights and obligations hereunder in connection with a Change of Control of Replimune.

19. <u>Invalid Provision</u>.

If any provision of this Agreement is held to be illegal, invalid or unenforceable, the remaining provisions shall remain in full force and effect and will not be affected by the illegal, invalid or unenforceable provision. In lieu of the illegal, invalid or unenforceable provision, the Parties shall negotiate in good faith to agree upon a reasonable provision that is legal, valid and enforceable to carry out as nearly as practicable the original intention of the entire Agreement.

20. <u>No Additional Obligations</u>.

Replimune and Regeneron have no obligation to renew this Agreement or apply this Agreement to any clinical trial other than each Study. Neither Party is under any obligation to enter into another type of agreement at this time or in the future.

21. Dispute Resolution and Jurisdiction.

21.1 The Parties shall attempt in good faith to settle all disputes arising out of or in connection with this Agreement or any Study Plan in an amicable manner. Any claim, dispute or controversy arising out of or relating to this Agreement or any Study Plan, including the breach, termination or validity hereof or thereof (each, a "**Dispute**"), shall be governed by and construed in accordance with the substantive laws of the State of New York, without giving effect to its choice of law principles.

21.2 Each Party irrevocably and unconditionally submits to the exclusive jurisdiction of the United States District Court for the Southern District of New York solely and specifically for the purposes of any action or proceeding arising out of or in connection with this Agreement (other than appeals therefrom), waives any objections to such jurisdiction and venue and agrees not to commence any action, suit or proceeding relating to this Agreement except in such courts.

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21.3 Nothing contained in this Agreement or any Study Plan shall deny either Party the right to seek injunctive or other equitable relief from a court of competent jurisdiction in the context of a bona fide emergency or prospective irreparable harm, and such an action may be filed or maintained notwithstanding any ongoing discussions between the Parties.

22. <u>Notices</u>.

All notices or other communications that are required or permitted hereunder shall be in writing and delivered personally, sent by facsimile (and promptly confirmed by personal delivery or overnight courier), or sent by internationally-recognized overnight courier addressed as follows:

Replimune Group, Inc. 18 Commerce Way Suite 4800 Woburn, Massachusetts 01801 Attention: Robert Coffin, CEO

With a copy to:

Replimune Group, Inc. 18 Commerce Way Suite 4800 Woburn, Massachusetts 01801 Attention: Pamela Esposito, CBO

If to Regeneron, to:

Regeneron Pharmaceuticals, Inc. 777 Old Saw Mill River Road Tarrytown, New York 10591 Attention: General Counsel

With a copy (which shall not constitute notice) to:

Regeneron Pharmaceuticals, Inc. 777 Old Saw Mill River Road Tarrytown, New York 10591 Attention: Vice President, Head of Business Development

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23. <u>Relationship of the Parties</u>.

The relationship between the Parties is and shall be that of independent contractors, and does not and shall not constitute a partnership, joint venture, agency or fiduciary relationship. Neither Party shall have the authority to make any statements, representations or commitments of any kind, or take any actions, which are binding on the other Party, except with the prior written consent of the other Party to do so. All persons employed by a Party will be the employees of such Party and not of the other Party and all costs and obligations incurred by reason of any such employment shall be for the account and expense of such Party.

24. <u>Counterparts and Due Execution</u>.

This Agreement and any amendment may be executed in two (2) or more counterparts (including by way of facsimile or electronic transmission), each of which shall be deemed an original, but all of which together shall constitute one and the same instrument, notwithstanding any electronic transmission, storage and printing of copies of this Agreement from computers or printers. When executed by the Parties, this Agreement shall constitute an original instrument, notwithstanding any electronic transmission, storage and printing of copies of this Agreement from computers or printers. For clarity, facsimile signatures and signatures transmitted via PDF shall be treated as original signatures.

25. <u>Construction</u>.

Except where the context otherwise requires, wherever used, the singular will include the plural, the plural the singular, the use of any gender will be applicable to all genders, and the word "or" is used in the inclusive sense (and/or). Whenever this Agreement refers to a number of days, unless otherwise specified, such number refers to calendar days. The captions of this Agreement are for convenience of reference only and in no way define, describe, extend or limit the scope or intent of this Agreement or the intent of any provision contained in this Agreement. The term "including" as used herein shall be deemed to be followed by the phrase "without limitation" or like expression. The term "will" as used herein means shall. References to "Article," "Section" or "Appendix" are references to the numbered sections of this Agreement and the appendices attached to this Agreement, unless expressly stated otherwise. Except where the context otherwise requires, references to this "Agreement" shall include the appendices attached to this Agreement. The language of this Agreement shall be deemed to be the language mutually chosen by the Parties and no rule of strict construction will be applied against either Party hereto.

[Remainder of page intentionally left blank.]

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IN WITNESS WHEREOF, the respective representatives of the Parties have executed this Agreement as of the Effective Date.

REPLIMUNE, INC

By: /s/ Robert Coffin

Robert Coffin

Name

Title CONFIDENTIAL *CONFIDENTIAL TREATMENT REQUESTED.
IN WITNESS WHEREOF, the respective representatives of the Parties have executed this Agreement as of the Effective Date. REGENERON PHARMACEUTICALS, INC.
By: /s/ Leonard Schleifer
Leonard Schleifer, MD, PhD
Name
Chief Executive Officer
Title
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Appendix A

FORM OF STUDY PLAN

Study Plan No. [·]

This Study Plan No. [·] ("**Study Plan No.** [·]") is governed by the terms of that certain Master Clinical Trial Collaboration and Supply Agreement in effect by and among is by and among Regeneron Pharmaceuticals, Inc., having a place of business at 777 Old Saw Mill River Road, Tarrytown, NY 10591 ("Regeneron"), and [Replimune Ltd. having a place of business at 18 Commerce Way, Woburn, MA 01801] ("**Replimune**"), dated [DATE], 2018 (the "**Agreement**"). Any item in this Study Plan No. [·] that is inconsistent with Sections 1-25 of the Agreement is invalid unless this Study Plan No. [·] expressly states that the Parties intend to amend a specific provision of Sections 1-25 of the Agreement and has been duly executed by appropriate authorized representatives of the Parties.

- (a) **Study Identifier** (including tumor type, line of therapy, study number):
- (b) **Study Effective Date**: [DATE]
- (c) **Sponsoring Party**: [PARTY]
- (d) **Project Manager**:
 - (i) Replimune:
 - (ii) Regeneron:
- (e) Wire Instructions:
 - (i) Replimune:
 - (ii) Regeneron:
- (f) **Protocol (or Protocol Synopsis)**: See Exhibit 1.
- (g) **Compound Supply**: See Exhibit 2.
- (h) Sample Analysis and Ownership and Sharing: See Exhibit 3.
- (i) **Clinical Obligations Schedule**: See Exhibit 4.
- (j) **Budget and Cost Share**: See Exhibit 5.
- (k) Press Release: See Exhibit 6. [NTD: Include only if Study is not the subject of a Press Release issued upon execution of the Master Agreement]

(l) Other dev	viations
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IN WITNESS WHEREOF,	the respective representatives of the Parties have executed this Study Plan No. $[\cdot]$ as of the Study Effective Date.
EPLIMUNE, INC.	
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Exhibit 3

SAMPLE ANALYSIS OWNERSHIP AND SHARING

[SEE ATTACHED]

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Exhibit 4

CLINICAL OBLIGATIONS SCHEDULE

[SEE ATTACHED]

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Exhibit 5

BUDGET AND COST SHARE

[SEE ATTACHED]

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Exhibit 6

PRESS RELEASE

[SEE ATTACHED]

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