

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

FORM 8-K

**CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934**

Date of Report (Date of earliest event reported): **October 20, 2020**

REPLIMUNE GROUP, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-38596
(Commission
File Number)

82-2082553
(IRS Employer
Identification Number)

**500 Unicorn Park
Woburn, MA 01801**
(Address of principal executive offices, including Zip Code)

Registrant's telephone number, including area code: **(781) 222-9600**

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value \$0.001 per share	REPL	The Nasdaq Stock Market LLC (Nasdaq Global Select Market)

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter). Emerging growth 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 pursuant to Section 13(a) of the Exchange Act.

Item 7.01 Regulation FD Disclosure.

On October 20, 2020, Replimune Group, Inc. (the “Company”) announced an updated corporate presentation and issued a press release relating to the announcement. This presentation includes information relating to the abstracts that were intended to be presented at the 2020 Society for Immunotherapy of Cancer Annual Meeting, including updated clinical trial data from the related trials, and other updated information about the Company. A copy of the presentation slides and the press release are furnished as Exhibits 99.1 and 99.2 to this Current Report on Form 8-K, respectively, and will be available on the Company’s website at www.replimune.com under “Investors and Media”. The Company undertakes no obligation to update, supplement or amend the materials attached hereto.

The information contained in this Item 7.01 and in the accompanying Exhibits 99.1 and 99.2 shall not be incorporated by reference into any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing, unless expressly incorporated by specific reference to such filing. The information in this Item 7.01 and the accompanying Exhibits 99.1 and 99.2 shall not be deemed to be “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section or Sections 11 and 12(a)(2) of the Securities Act of 1933, as amended.

Item 8.01 Other Events.*Phase 2 Clinical Trial of RP1*

We recently announced updated clinical data from our multi-cohort Phase 1/2 clinical trial evaluating RP1 in combination with nivolumab in patients with melanoma and non-melanoma skin cancers. RP1 in combination with nivolumab has continued to be well tolerated, and we believe demonstrates continued promising efficacy signals in patients with skin cancers, including in patients with CSCC and those with anti-PD-1 refractory and other difficult-to-treat melanomas.

As of October 15, 2020, we have enrolled 36 melanoma and 20 non-melanoma skin cancer patients in this clinical trial, 18 of whom are evaluable for efficacy. In order to be evaluable for efficacy in this clinical trial, a patient must have had at least one follow up scan or disease progression before the first follow up scan. Patients received up to eight doses of RP1 (up to 10 mL per visit once every two weeks, with a first dose of 10^6 PFU/mL followed by 10^7 PFU/mL) and nivolumab (240mg once every two weeks for four months followed by 480mg once every four weeks for up to two years) from the second RP1 dose. Of the 36 melanoma patients, 16 cutaneous melanoma patients had previously received anti-PD-1 (eight of whom had also previously received anti-CTLA-4), eight cutaneous melanoma patients were naïve to anti-PD-1 therapy, six patients had mucosal melanoma, and six patients had uveal melanoma. At the data cut-off date, five patients with cutaneous melanoma who had received prior anti-PD-1 therapy had responses (four partial responses and one complete response), four of whom also received prior anti-CTLA-4 therapy. An additional patient is classified as a surgical complete response and one patient remains on study with stable disease, having neither progressed nor met the formal definition for response. Further, four patients (two complete responses and two partial responses) with anti-PD-1 naïve cutaneous melanoma and two patients with mucosal melanoma (one of whom had prior anti-PD-1 therapy and achieved a complete response) had achieved responses. Of the 18 non-melanoma skin cancer patients evaluable for efficacy, 11 patients had CSCC, three had basal cell carcinoma, one had Merkel cell carcinoma, and three had angiosarcoma. At the data cut-off date, two patients with angiosarcoma had achieved response and eight patients with CSCC had achieved response, with five CSCC patients having achieved a complete response. An additional CSCC patient had stable disease at the time of the patient’s first scan with treatment continuing. Across all cohorts all responses are ongoing at out to approximately 20 months from the start of treatment with the exception of one CSCC patient and one anti-PD-1 refractory melanoma patient. Follow-up data for one responding angiosarcoma patient who stopped nivolumab therapy due to nivolumab side effects have currently not been obtained, and continuing response status is unknown. Adverse events remained consistent with those observed during the Phase 1 clinical trial, with RP1 side effects generally of Grade 1 or 2 constitutional-type symptoms with less frequent Grade 3 side effects and no exacerbation of the side effects expected for nivolumab alone. Tumor biopsies in patients have continued routinely to show immune activation, including robust recruitment of CD8+ T cells, reversal of T cell exclusion, and increased PD-L1 expression.

Unless otherwise noted herein, clinical data contained herein are provided as of October 15, 2020.

Phase 1 Clinical Trial of RP2

We also recently announced initial single-agent RP2 data from our Phase 1 clinical trial of RP2 alone and in combination with nivolumab in patients with solid tumors. In this Phase 1 clinical trial, we are assessing initial tolerability of RP2 in solid tumors and determining the recommended Phase 2 dose of RP2 to be administered alone and then evaluating in combination with nivolumab. We believe these initial Phase 1 clinical data support the safety and efficacy of single-agent RP2, including demonstrating responses in injected and uninjected tumors in patients with difficult to treat, heavily pre-treated and immune insensitive advanced cancers. In addition, we believe these data support our hypothesis that anti-CTLA-4 expressed from RP2 and combined with oncolytic virus replication, with accompanying antigen release and presentation, can induce potent anti-tumor immune responses.

In the dose-escalation portion of this clinical trial, patients were treated with single-agent RP2 using a 3+3 dose escalation at two dose levels of up to 10 mL of RP2 once every two weeks, up to five times. The first dose level was 10^5 PFU/mL for the initial dose followed by four doses of 10^6 PFU/mL, and the second dose level was 10^6 PFU/mL for the initial dose followed by four doses of 10^7 PFU/mL. Lesions were directly injected or imaging guidance was used for visceral lesions and tumor biopsies were obtained for biomarker analysis. Viral shedding and anti-HSV-1 antibody titers were also monitored. As the first six patients were all HSV seropositive per the protocol, an additional three HSV seronegative patients were enrolled as per the protocol.

As of October 15, 2020, nine patients have been enrolled in the dose-escalation portion of this clinical trial and received single agent RP2. Of the nine patients treated with single agent RP2, three have ongoing responses at between 8 to 11 months from the start of treatment (one complete response and two partial responses) and a further patient remains on study with the response status continuing to be monitored. The objective responses were observed in patients with uveal melanoma, mucoepidermoid carcinoma of the parotid, and esophageal cancer. A further patient with micro satellite (immune intensive) colorectal cancer remains on study and the response status continues to be monitored. The other five patients enrolled into the clinical trial are no longer being followed due to progressive disease. Adverse events were primarily Grade 1 or 2, including febrile and other constitutional symptoms, local inflammation, and erythema, with rarer Grade 3 side effects being observed. There were no dose-limiting toxicities requiring dose level expansion. The recommended Phase 2 dose was selected as up to 10 mL of 10^6 PFU/mL followed once every two weeks by multiple doses of 10^7 PFU/mL.

We have initiated enrollment in a combination cohort with nivolumab of up to 30 patients to be dosed up to eight times at the Phase 2 dose level of RP2 in combination with nivolumab from the second RP2 dose (240mg once every two weeks for four months from the second RP2 dose, followed by 480mg once every four weeks for 20 months). Ten patients have been enrolled to date with no dose limiting toxicities, with none having yet been evaluated for efficacy.

Unless otherwise noted herein, clinical data contained herein are provided as of October 15, 2020.

Preliminary financial estimate

We preliminarily estimate that as of September 30, 2020, we had approximately \$244.6 million in cash and cash equivalents and short-term investments. We believe that our existing cash and cash equivalents and short-term investments along with our debt commitments will enable us to fund our operating expenses and capital expenditure requirements to mid-2023.

This amount is unaudited and preliminary, and does not present all information necessary for an understanding of our financial condition as of September 30, 2020. The review of our condensed consolidated financial statements for the three and six months ended September 30, 2020 is ongoing and could result in changes to this amount due to the completion of financial closing procedures, final adjustments and other developments that may arise between now and the time the condensed consolidated financial statements for the three and six months ended September 30, 2020 are finalized and publicly released. Our independent registered public accounting firm, PricewaterhouseCoopers LLP, has not audited, reviewed, compiled or performed any procedures with respect to the preliminary financial estimate, and does not express an opinion or any other form of assurance with respect thereto. The preliminary financial estimate presented above has been prepared by and is the responsibility of management. Estimates of financial results are inherently uncertain and subject to change, and we undertake no obligation to update this information. In addition, the estimated balance of cash and cash equivalents and short-term investments as of September 30, 2020 is not necessarily indicative of future performance or any other period, including the results to be achieved for the remainder of the fiscal year ending March 31, 2021 or any future period.

Item 9.01 Financial Statements and Exhibits.

Exhibit No.	Description
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99.1	Company Presentation dated October 20, 2020
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99.2	News Release dated October 20, 2020
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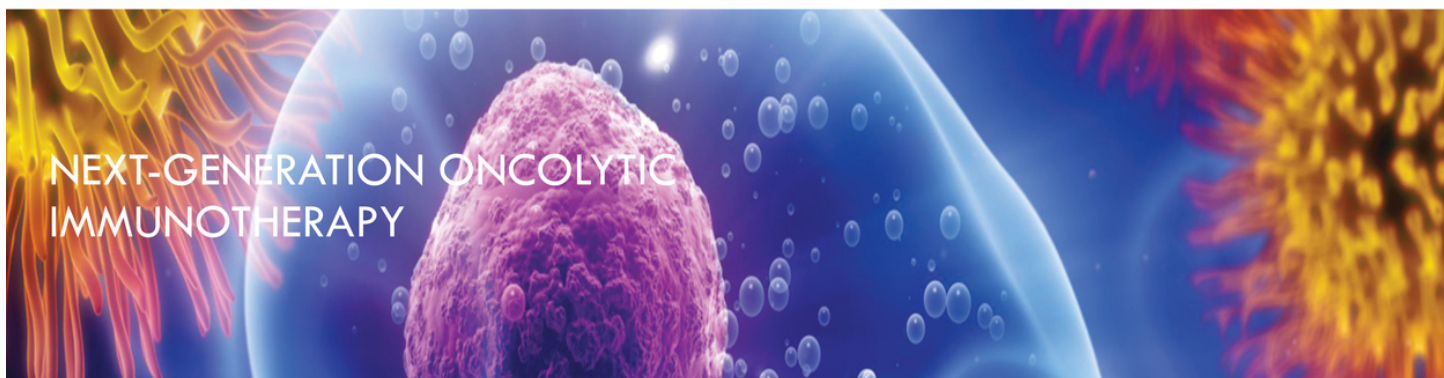
SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

REPLIMUNE GROUP, INC.

Date: October 20, 2020

By: /s/ Jean Franchi
Jean Franchi
Chief Financial Officer



NEXT-GENERATION ONCOLYTIC
IMMUNOTHERAPY

October 2020

Safe harbor

Any statements contained herein that are not statements of historical facts may be deemed to be forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, including statements regarding the advancement of our clinical trials, patient enrollments in our existing and planned clinical trials and the timing thereof, the results of our clinical trials, the timing and release of our clinical data, our goals to develop and commercialize our product candidates, our expectations regarding the size of the patient populations for our product candidates if approved for commercial use, our preliminary financial estimates as of September 30, 2020, and other statements identified by words such as “could,” “expects,” “intends,” “may,” “plans,” “potential,” “should,” “will,” “would,” or similar expressions and the negatives of those terms. Forward-looking statements are not promises or guarantees of future performance, and are subject to a variety of risks and uncertainties, many of which are beyond our control, and which could cause actual results to differ materially from those contemplated in such forward-looking statements. These factors include risks related to our limited operating history, our ability to generate positive clinical trial results for our product candidates, the costs and timing of operating our in-house manufacturing facility, the timing and scope of regulatory approvals, changes in laws and regulations to which we are subject, competitive pressures, our ability to identify additional product candidates, political and global macro factors including the impact of the SARS-COV-2 coronavirus as a global pandemic and related public health issues, and other risks as may be detailed from time to time in our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, and other reports we file with the Securities and Exchange Commission. Our actual results could differ materially from the results described in or implied by such forward-looking statements. Forward-looking statements speak only as of the date hereof, and, except as required by law, we undertake no obligation to update or revise these forward-looking statements.

Proprietary 'Immulytic' oncolytic immunotherapy platform

- Intended to maximally activate the immune system against a patient's cancer
- Intended to establish Replimune's products as the second cornerstone of immuno-oncology
- Systemically active - generates robust reductions of injected and uninjected tumors

RP1 – in multiple clinical trials, with current focus on immune-responsive tumor types

- Lead indication – advanced cutaneous squamous cell carcinoma (CSCC)
 - Strong Phase 2 data (ORR and durability) from single-arm study of RP1 in combination with Opdivo
 - Expanding into CSCC patients who have failed prior anti-PD1 therapy
 - Registration-directed randomized controlled clinical trial in combination with Libtayo enrolling
- Anti-PD1 failed melanoma
 - Strong Phase 2 (ORR and durability) data from RP1 in combination with Opdivo
 - 125 patient potentially registrational cohort enrolling
- 30 patient anti-PD1 failed non-small cell lung cancer cohort expected to initiate around year-end 2020

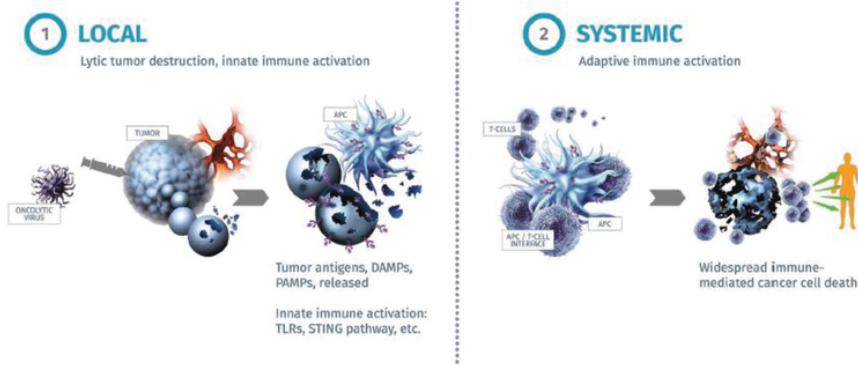
RP2 & RP3 – intended to treat less immune-responsive tumor types

- Strong Phase 1 data (ORR and durability) with single agent RP2
 - Demonstrating utility in heavily pre-treated immune insensitive tumor types
- RP3 intended to enter the clinic by year-end 2020 (CTA obtained)

Oncolytic immunotherapy

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- The use of viruses that selectively replicate in & kill tumors to treat cancer
 - Highly inflammatory: Activates both innate and adaptive immunity
 - Systemically activates the immune system against the tumor antigens released
 - Can be 'armed' with additional genes to augment the natural properties of the virus with additional mechanisms of action
 - Off-the-shelf
- Single agent T-VEC is clinically validated & FDA approved



Replimune's product design objectives & solutions

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1. Maximize direct tumor destruction & immunogenic cell death through design and development of a virus with the best ability to infect, replicate in & kill tumor cells:
 - *Based on a potent new clinical HSV strain resulting from a comprehensive screen**
 - *ICP34.5 deleted for selectivity, US11 upregulated to retain near wild type replication in tumors**
 - *Encodes a potent fusogenic protein, increasing killing & immunogenic cell death 10-100 fold**
 - *Together providing maximal antigen presentation ('Signal 1')*
 - *Our platform for all our product candidates from which additional transgenes are then expressed*
2. Further arm with immune activating transgenes intended to maximize T cell co-stimulation ([Signal 2](#)) & systemic immune activation (including through induction of inflammatory cytokines: [Signal 3](#))
 - *GM-CSF – DC expansion & maturation: **RP1, RP2***
 - *Anti-CTLA-4 – block APC/T-cell feedback loop: **RP2, RP3***
 - *CD40L & 4-1BBL – Activate co-stimulation; induce inflammatory cytokines (IL-2, IL-8, IL-12): **RP3***

* Replimune's fusion-enhanced backbone virus is described in Thomas et al (2019) JITC 10; 214

Practical and comprehensive activation of a tumor specific immune response

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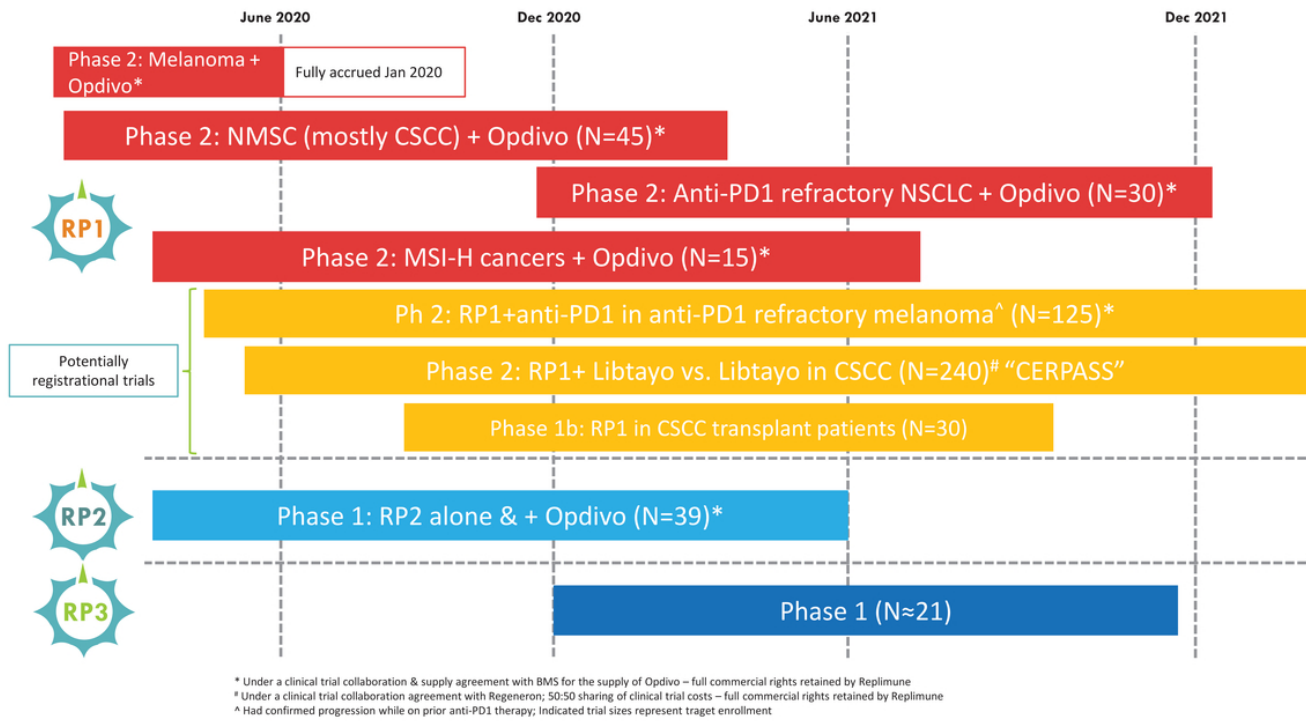
Our platform offers significant advantages compared to competing approaches, such as cell-based therapies, including TILs, and personalized cancer vaccines

	Replimune's Immulytic platform	Cell-based therapy (including TILs)	Personalized cancer vaccines
"Off the shelf" – no patient-specific manufacturing	✓	✗	✗
Commercially attractive COGS	✓	✗	✗
Incorporates multiple modalities (incl. innate & adaptive immunity)	✓	✗	✗
Desirable safety profile, without a high frequency of high-grade side effects including death	✓	✗	✓
Potentially applicable to nearly all patients with solid tumors	✓	✗	✗



Replimune's development plan

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RP1 - Lead indication overview: CSCC

- The second most common skin cancer with $\approx 700,000$ patients annually in the U.S.¹
- Approximately 7,000-15,000 US deaths annually¹⁻³
 - Most conservative addressable population
 - 80% of patients die from locoregional progression, not metastatic disease^{4,5}
- Potential US market estimated at 7,000-28,000 patients annually¹⁻⁴
- While effective, anti-PD1 therapy alone results in only a low rate of complete response

	Libtayo				Keytruda	Opdivo
	Locally advanced		metastatic		47 locally advanced + 58 metastatic	4 locally advanced, 16 locoregional, 4 metastatic
Patient population						
Number of patients	33 (per label, 2018)	78 (ASCO 2020)	75 (per label, 2018)	59 (ASCO 2020)	105 (ESMO 2019)	24 (ASCO 2020)
ORR	48.5%	45%	46.7%	51%	34.3%	54.5%
CR	0%	13%	5.3%	20%	3.8%	0%

¹Rogers et al JAMA Dermatol 10 2015

²Clayman et al JCO 23 2005

³Mansouri et al J Am Acad Dermatol 153 2017

⁴Schmults et al JAMA Dermatol 149 2013

⁵Motaparthi et al Adv Anat Pathol 24 2017



- Registration-directed randomized controlled Phase 2 clinical trial in collaboration with Regeneron*
 - 240 patients (target enrollment) with locally advanced or metastatic CSCC naïve to anti-PD1 therapy
 - Randomized 2:1 (RP1+ Libtayo vs. Libtayo alone)
 - Primary endpoint ORR
 - Secondary endpoints include CR rate, duration of response, PFS, OS
 - Aim to show $\geq 15\%$ delta improvement in ORR
 - Control arm ORR expectation based on anti-PD1 single agent data 34-51%
 - Control arm CR expectation based on anti-PD1 single agent data $< 10\%$ at data cut off
 - Aim to also improve durability and show multi-fold (2-3x) improvement in CR rate
 - * Under a clinical trial collaboration agreement with Regeneron; 50:50 sharing of clinical trial costs – full commercial rights retained by Replimune
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Compelling activity with RP1 in combination with nivolumab in non-melanoma skin cancers, particularly CSCC

Best response

Efficacy evaluable population (Patients with follow up scans or PD)

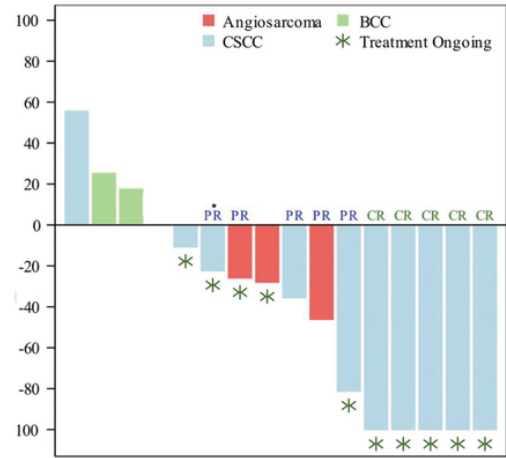
	CSCC	BCC	Merkel cell carcinoma	Angiosarcoma
Number of patients	11	3	1	3
Best overall response n (%)				
CR	5 (45.5)	0	0	0
PR	3* (27.3)	0	0	2 (66.7)
SD	1# (9.1)	2 (66.7)	0	1 (33.3)
PD	2 (18.2)	1 (33.3)	1 (100)	0
ORR	8 (72.7)	0	0	2 (66.7)
CR+PR+SD	9 (81.8)	2 (67.7)	0	3 (100)
DOR (mos.)		NA	NA	
Median	>4.66			
Range	>0.03->16.93			>0.03-NA^

*One patient PR by clinical assessment; CT pending #Just had first scan, newly added to the denominator
^Follow up for one patient not available post discontinuation for nivolumab-related side effects

Cohort being expanded from 30 to 45 patients to include patients who have failed prior anti-PD1 therapy

Maximum percent tumor reduction

Patients with follow up scans



* PR by clinical assessment; CT pending

CSCC patient 4402-2001 - ongoing CR

16th June 2019
(baseline)

1st July 2019
(post one dose of RP1, no
Opdivo)

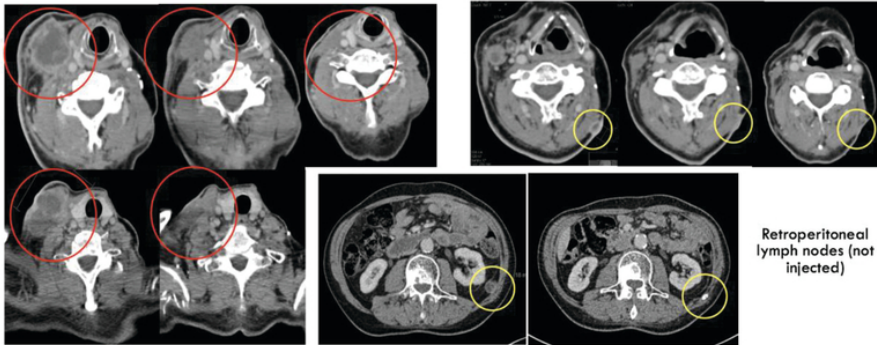
16th July 2019
(post 2 doses of RP1 & 1 dose
of Opdivo)



- Recurrent CSCC of the neck (bilateral), previously treated with cisplatin-based chemoradiation & six cycles of carboplatin/5-FU
- Both the large injected tumor & the smaller contralateral tumor in the neck reduced considerably before the first Opdivo dose, i.e. after the first dose of RP1

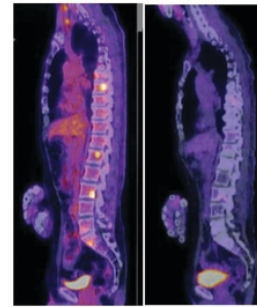
Baseline Right neck (injected)
8 weeks 24 weeks

Baseline Left neck (not injected)
8 weeks 16 weeks

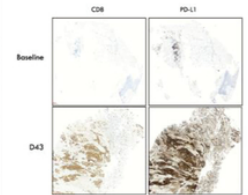


Retroperitoneal lymph nodes (not injected)

June 2018 Feb 2020



Bone metastases

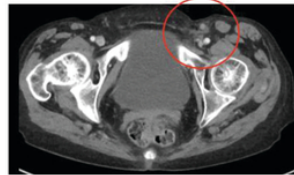
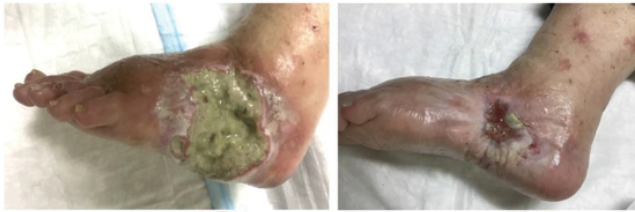


New responses in CSCC since last reported in June 2020

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22nd May 2020

12th October 2020



Screening

17th Aug 2020

Pt 1122-2014 - PR (clinically assessed October 12th 2020; October CT pending)

- Patient had enlarged groin node metastases that were initially injected & responded, as well as response in the distant foot tumor prior to its subsequent injection

12th May 2020
(Baseline)

26th May 2020
(pre Opdivo)

9th June 2020

8th September 2020



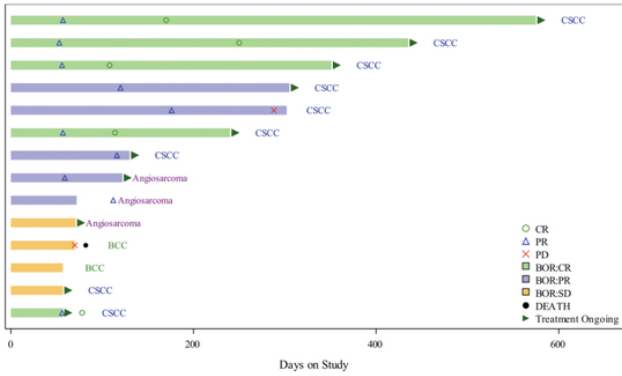
Pt 1121-2003 - CR

- Prior cetuximab
- Injections into left neck lesion

Responses in CSCC remain deep & durable

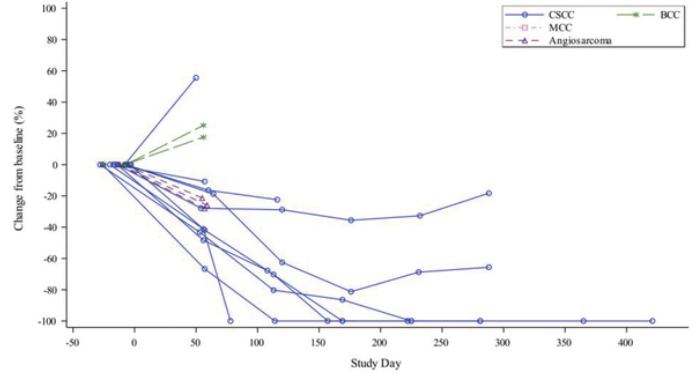
Duration of best response

Patients with a best response of at least SD



% Change from baseline in sum of tumor diameters over time

Patients with at least one follow up assessment



Based on the data to date, Replimune believes it is well positioned for success in the potentially registrational Phase 2 clinical trial of RP1 combined with Libtayo in CSCC



- Approximately half of advanced melanoma patients still die of their disease, despite multiple approved therapies now being available
 - Anti-PD1, anti-CTLA-4, combined anti-CTLA-4/anti-PD1, BRAF targeted agents
- Approximately 7,230 US deaths annually from metastatic melanoma¹
- Approximately 62,000 deaths annually world-wide²

- High unmet medical need for patients who fail anti-PD1 based therapy
- 40-65% of all metastatic melanoma are primary refractory to initial anti-PD1 therapy³
- Expected response rate to continued treatment with anti-PD1 therapy following confirmed progression on single agent anti-PD1 is 6-7%⁴
- The expected response rate to Yervoy following failure of initial single agent anti-PD1 is 13%⁵

¹ <https://seer.cancer.gov> (2019 data). ²JAMA Oncol. 2019; 5(12):1749-1768. ³ Gide et al Clin. Cancer Res **24** 2018

⁴ Ribas et al Lancet Oncology **19** 2018; Hodi et al JCO **34** 2016 ⁵ Pires de Silva et al ASCO 2020

RP1 in anti-PD1 failed melanoma data

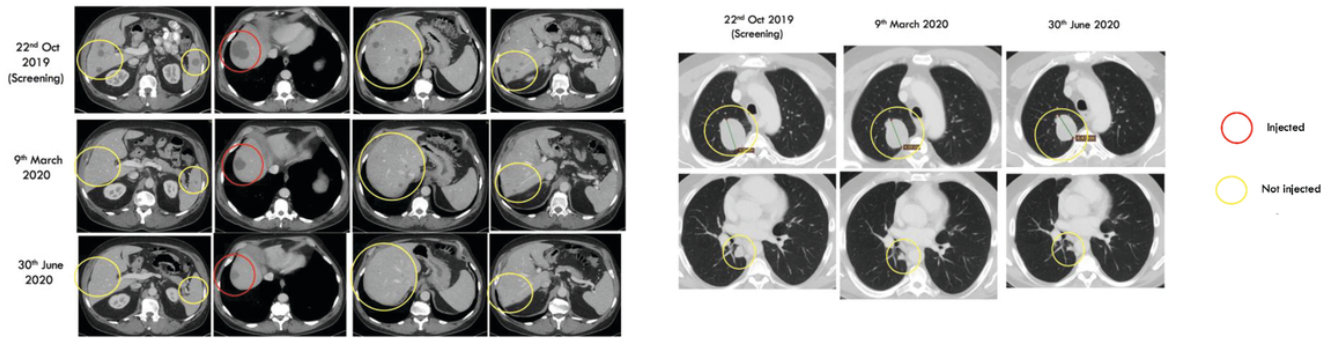
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- October 15th 2020 status of the anti-PD1 failed cutaneous melanoma (N=16) patients dosed
 - 87.5% stage IVM1b/ M1c ; very advanced visceral disease population
 - Nine patients showed initial clinical benefit*
 - Five patients have met the formal criteria for response; 1 CR, 4 PR
 - Four of which had previously failed both anti-PD1 and anti-CTLA-4 therapies
 - Responses are deep and durable ; 80% ongoing at out to over 12 months
 - Current ORR for these patients remains at 31%
 - Of two patients that had not responded or progressed as of June 2020 data disclosure
 - One is now an ongoing surgical CR (counted as SD per study protocol definitions)
 - One remains SD, with treatment ongoing
 - Clinical data supported by biomarker data, including reversal of T cell exclusion
- Activity also seen in patients who have failed prior anti-PD1 therapy with uveal and mucosal melanoma

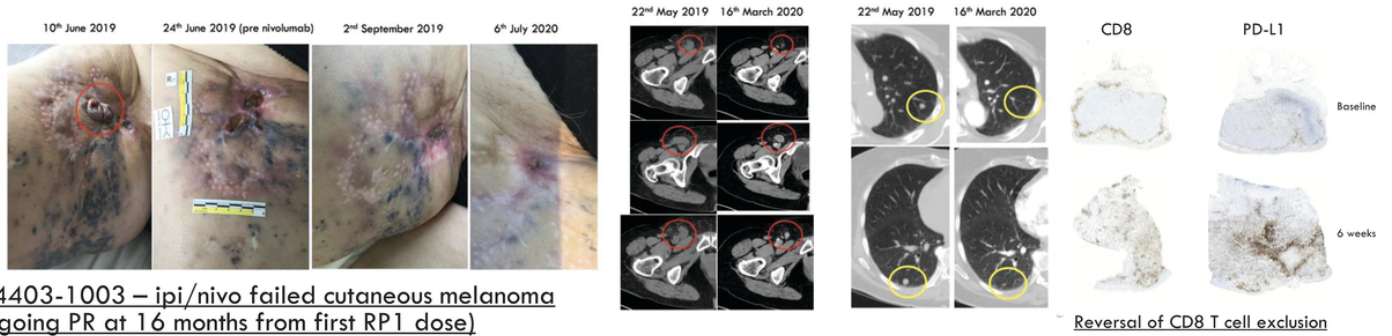
*SD or better with evidence of anti-tumor activity

Local & distant responses in ipi/nivo failed melanoma

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Pt 1122-2007 – ipi/nivo failed cutaneous melanoma (ongoing PR at 11 months from first RP1 dose)

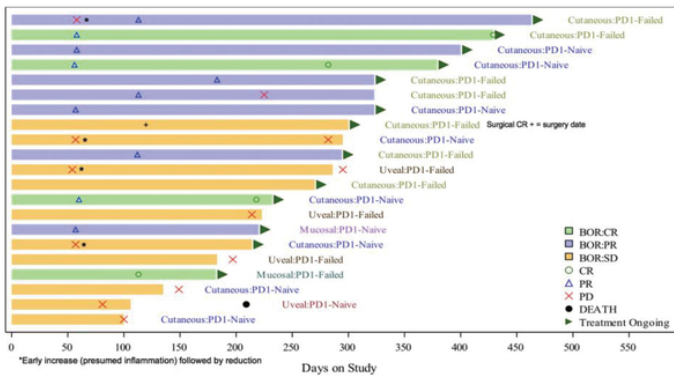


Pt 4403-1003 – ipi/nivo failed cutaneous melanoma (ongoing PR at 16 months from first RP1 dose)

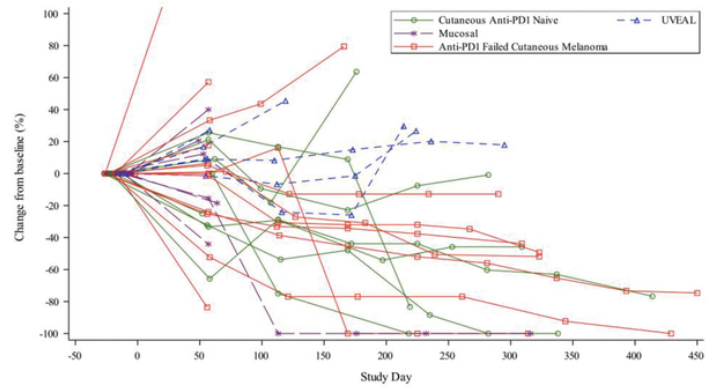
Reversal of CD8 T cell exclusion

Responses are deep & durable, including for anti-PD1 failed melanoma

Duration of best response
Patients with a best response of at least SD



% Change from baseline in sum of tumor diameters over time
Patients with at least one follow up assessment



Extended clinical benefit also seen in patients with a best response of SD

Based on the data to date, Replimune believes it is well positioned for success in the potentially registrational 125 patient Phase 2 cohort of RP1 combined with nivolumab in anti-PD1 failed melanoma

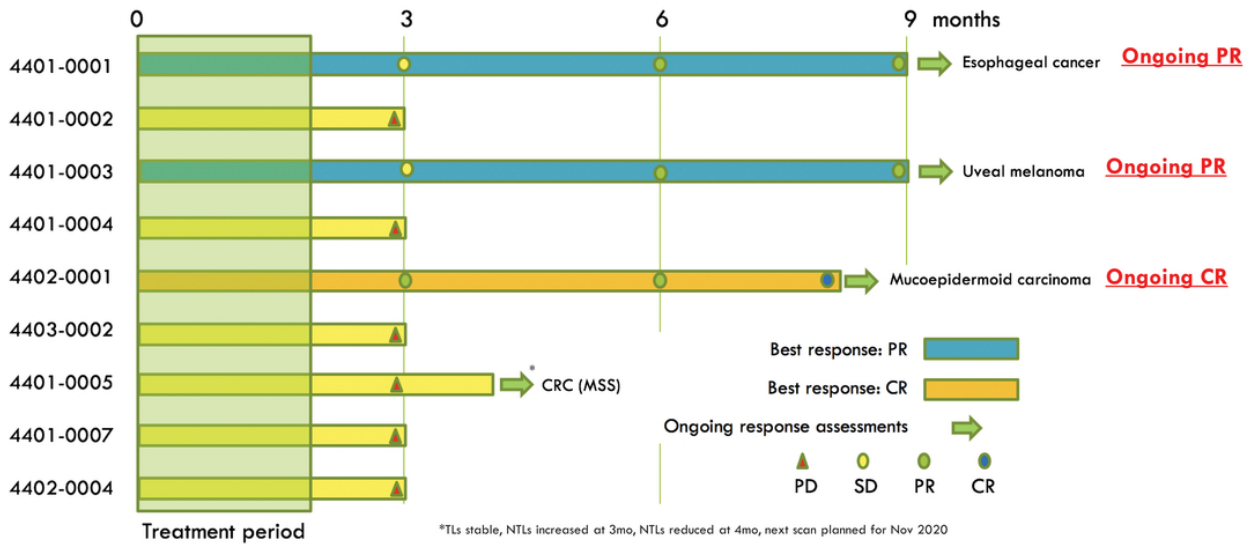
RP2 – Single agent activity clearly demonstrated

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- RP2 – leverages Replimune's platform to additionally express an anti-CTLA-4 antibody
- Well tolerated; side effects consistent with RP1
- Compelling single agent efficacy in heavily pre-treated patients with less immune sensitive & immune insensitive tumor types
 - CR – Mucoepidermoid carcinoma
 - PR – Uveal melanoma
 - PR – Esophageal cancer
- Kinetics of response suggests initial tumor inflammation precedes response
 - Similar pattern may be developing in a further patient
 - MSS (immune insensitive) colorectal cancer
- Responses are durable & all are ongoing with patients at between 8 & 11 months from first RP2 dose
- Treatment of patients with RP2 combined with Opdivo is underway
 - Patients not yet evaluable for efficacy but well tolerated so far



RP2 single agent – Deep and durable responses



Kinetics of response following treatment with single agent RP2

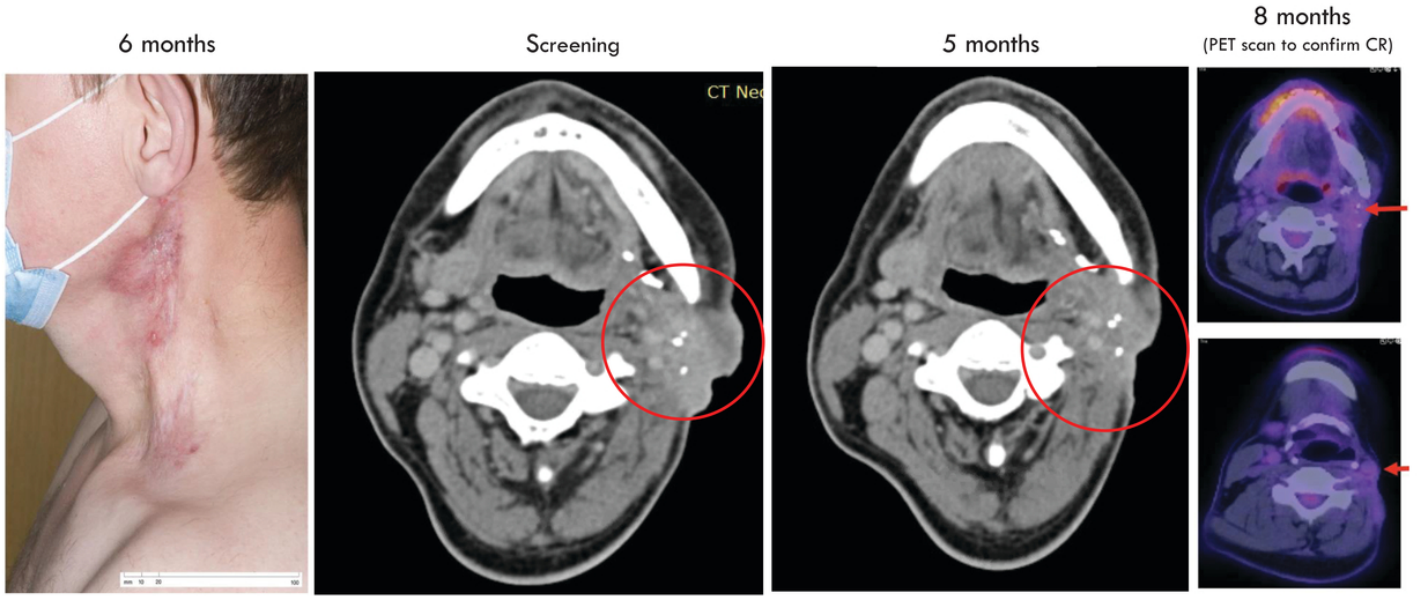
Other patients had advanced, heavily pre-treated uveal melanoma x2, head & neck cancer & cutaneous melanoma x2



Patient #: 4402-0001: Mucoepidermoid carcinoma of the parotid – Ongoing CR

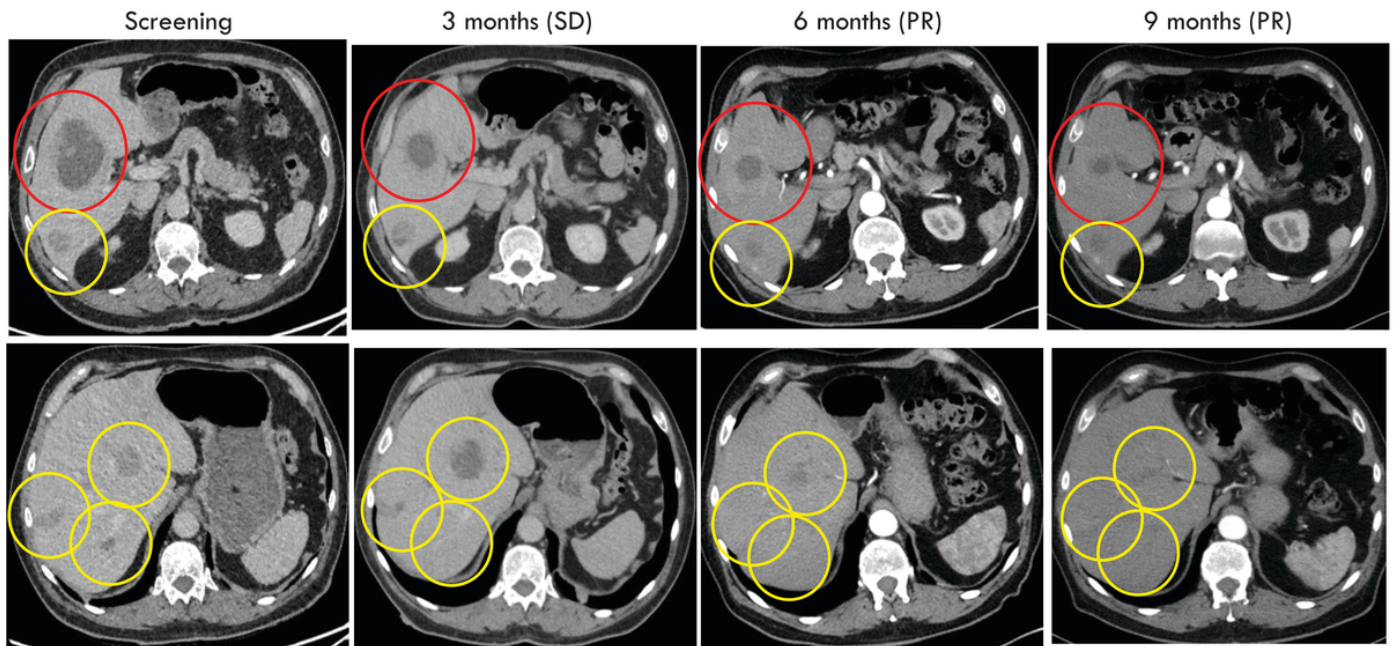


- Prior therapies: Carboplatin/paclitaxel, bicalutamide, ceralasertib
- Cervical lymph node & supraclavicular fossa injected with 10ml 1×10^6 pfu/ml, then 10ml 1×10^7 pfu/ml x4 Q2W
- CR confirmed by PET scan 16th Oct 2020



Patient #: 4401-0003: Uveal melanoma (ipi/nivo failed) – Ongoing PR

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- Extensive liver metastases (others not shown)
- Prior therapies: Ipilimumab/nivolumab
- Largest liver lesion injected with 3ml 1×10^5 pfu/ml, then 3mL 1×10^7 pfu/ml x4 Q2W

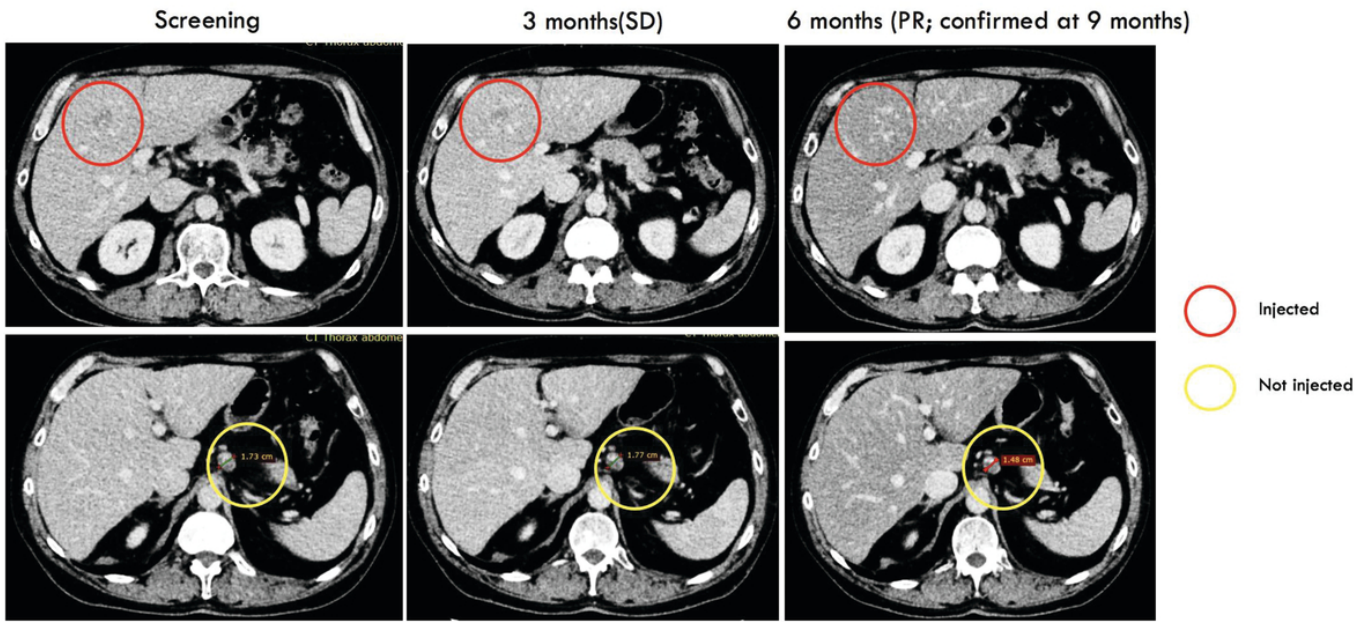
○ Injected

○ Not injected



Patient #: 4401-0001: Esophageal cancer (anti-PD-L1 failed) – Ongoing PR

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- Liver & abdominal lymph node metastases
- Prior therapies: Durvalumab (anti-PD-L1), M6620 (ATR kinase inhibitor), capecitabine, oxaliplatin, cisplatin, chemoradiation
- Liver lesion injected with 1ml 1×10^5 pfu/ml, then 0.5mL 1×10^6 pfu/ml x4 Q2W

Critical focus on manufacturing

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- For registration directed studies & commercialization, in-house manufacturing in place
- The team has extensive manufacturing experience
- 63,000 ft² manufacturing facility constructed
 - State of the art facility
 - Fully fitted out; three tech transfer runs successfully completed
 - Scale sufficient to cover global commercialization of Replimune's products at full capacity
- Product expected to be released for use in 2021 to incorporate into clinical trials intended for registration



Summary/Looking ahead*

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- RP1 - CSCC
 - Compelling data with RP1 combined with nivolumab
 - NMSC cohort expansion to 45 patients to include anti-PD1 failed patients
 - Potentially registrational randomized trial underway – primary readout expected in 2022
- RP1 - Anti-PD1 failed melanoma
 - Compelling data with RP1 combined with nivolumab
 - Potentially registrational 125 patient cohort underway – primary readout expected in 2022
- RP1 – Anti-PD1 failed NSCLC
 - Cohort to open by approx. year-end 2020
- Evidence of activity with RP1 also seen in other tumor types
- RP2 – Strong single agent data generated
 - Opens the way to immune insensitive tumor types – indication prioritization underway
- RP3 - Phase 1 clinical trial expected to initiate by year-end 2020

*COVID-19 has impacted & is expected to continue to impact accrual & therefore the number of patients from whom data is expected to be available during 2020, with average expected length of follow up also expected to be reduced.



Replimune Releases Updated Corporate Presentation

Woburn, MA, October 20, 2020 – Replimune Group, Inc. (NASDAQ: REPL), a biotechnology company developing oncolytic immuno-gene therapies derived from its Immulytic™ platform, announced that it is filing a Current Report on Form 8-K with the Securities and Exchange Commission (SEC), in which it will furnish an updated corporate presentation. The presentation can be found in the “Investors and Media” section of Replimune’s corporate website under the “Events and Presentations” section ([Link to Presentation](#)).

The presentation includes information relating to the abstracts that are to be presented at the 2020 Society for Immunotherapy of Cancer (SITC) Annual Meeting, including updated clinical trial data from the related trials, and other updated information about Replimune. The data from these abstracts appeared briefly and in error on the SITC website on October 14, 2020, prior to their intended release on November 9, 2020. As a result, the full abstracts were released by Replimune on that date, and are being followed up with data in Replimune’s updated corporate presentation today.

About Replimune

Replimune Group, Inc., headquartered in Woburn, MA, was founded in 2015 to develop the next generation of oncolytic immune-gene therapies for the treatment of cancer. Replimune is developing novel, proprietary therapeutics intended to improve the direct cancer-killing effects of selective virus replication and the potency of the immune response to the tumor antigens released. Replimune’s Immulytic™ platform is designed to maximize systemic immune activation, in particular to tumor neoantigens, through robust viral-mediated immunogenic tumor cell killing and the delivery of optimal combinations of immune-activating proteins to the tumor and draining lymph nodes. The approach is expected to be highly synergistic with immune checkpoint blockade and other approaches to cancer treatment across a broad range of cancers. Replimune intends to progress these therapies rapidly through clinical development in combination with other immuno-oncology products with complementary mechanisms of action. For more information, please visit www.replimune.com.

Forward Looking Statements

This press release contains forward looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, including statements regarding our expectations about our cash runway, the advancement of our clinical trials, our plans to initiate new clinical trials, our goals to develop and commercialize our product candidates, patient enrollments in our existing and planned clinical trials and the timing thereof, the potential impact of COVID-19 on our operations and milestones, and other statements identified by words such as “could,” “expects,” “intends,” “may,” “plans,” “potential,” “should,” “will,” “would,” or similar expressions and the negatives of those terms. Forward-looking statements are not promises or guarantees of future performance, and are subject to a variety of risks and uncertainties, many of which are beyond our control, and which could cause actual results to differ materially from those contemplated in such forward-looking statements. These factors include risks related to our limited operating history, our ability to generate positive clinical trial results for our product candidates, the costs and timing of operating our in-house manufacturing facility, the timing and scope of regulatory approvals, changes in laws and regulations to which we are subject, competitive pressures, our ability to identify additional product candidates, political and global macro factors including the impact of the coronavirus as a global pandemic and related public health issues, and other risks as may be detailed from time to time in our Annual Reports on Form 10-K and Quarterly Reports on Form 10-Q and other reports we file with the SEC. Our actual results could differ materially from the results described in or implied by such forward-looking statements. Forward-looking statements speak only as of the date hereof, and, except as required by law, we undertake no obligation to update or revise these forward-looking statements.

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