Replimune Enters into Clinical Collaboration Agreement with Roche for the Development of RP3 In Colorectal Cancer and Hepatocellular Carcinoma

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RP3 will be developed in combination with atezolizumab and bevacizumab for the third-line treatment of colorectal cancer (CRC) and for the first- and second-line treatment of hepatocellular carcinoma (HCC)

Includes cost sharing for development in third-line CRC and second-line HCC

WOBURN, Mass., Dec. 07, 2022 (GLOBE NEWSWIRE) -- Replimune Group, Inc. (NASDAQ: REPL), a clinical stage biotechnology company pioneering the development of a novel class of tumor-directed oncolytic immunotherapies, today announced that the Company has entered into a Master Clinical Trial Collaboration and Supply Agreement in relation to Replimune's RP2/3 program in colorectal cancer (CRC) and hepatocellular carcinoma (HCC). Specifically, the companies will collaborate in third-line (3L) CRC and in first- and second-line (1L & 2L) HCC. Under the terms of the agreement, the companies will share costs and Roche will supply its currently approved drugs, atezolizumab and bevacizumab for 2L HCC and 3L CRC combined with RP3. Roche will also supply atezolizumab and bevacizumab for 1L HCC combined with RP3, and for 3L CRC combined with RP2. Approximately 30 patients will be enrolled within each cohort. Replimune will have responsibility for operationalizing the clinical trial.

Atezolizumab in combination with bevacizumab is FDA approved and the current standard of care for the 1L treatment of unresectable HCC, with current treatment options for the treatment of 2L HCC being very limited. Combining RP3 with atezolizumab and bevacizumab has the potential to increase response rates and clinical benefit for patients with 1L disease, and to provide a much needed option for patients with 2L disease. While, bevacizumab is FDA approved to treat metastatic colorectal cancer, or mCRC, for first- or second-line treatment in combination with chemotherapy, late line CRC is a significant unmet need.

"This collaboration announcement is in keeping with our philosophy of partnering with industry leaders in oncology and in indications where our immunotherapies have the potential to become a key cornerstone of treatment," said Pamela Esposito, Ph.D., Chief Business Officer of Replimune. "With similar collaborations already in place for our lead candidate RP1 with Regeneron and Bristol-Myers Squibb, we believe this latest cost and supply sharing collaboration with Roche, a leader in GI cancers, will help us efficiently advance RP2/3 for the development of CRC and HCC."

Replimune remains on track to initiate its Phase 2 development program with RP2/3 in the first half of 2023. As previously announced, this program is intended to include Phase 2 clinical trials in squamous cell carcinoma of the head and neck (SCCHN; locally advanced and recurrent/metastatic), hepatocellular carcinoma (HCC; first line and second line) and colorectal cancer (CRC; third line), combined with current standard of care where appropriate.

About RP2 & RP3
RP2 and RP3 are enhanced potency oncolytic versions of HSV that express a fusogenic glycoprotein which provides robust immunogenic cell death together with additional immune-activating proteins. RP2 additionally expresses an anti-CTLA-4 antibody-like molecule and GM-CSF and RP3 additionally expresses the anti-CTLA-4 antibody-like molecule and the immune co-stimulatory pathway activating proteins CD40L and 4-1BBL. RP2 and RP3 are intended to provide targeted and potent delivery of these proteins to the sites of immune response initiation in the tumor and draining lymph nodes, with the goal of focusing systemic immune-based efficacy on tumors and limiting off-target toxicity.

About Replimune
Replimune Group, Inc., headquartered in Woburn, MA, was founded in 2015 with the mission to transform cancer treatment by pioneering the development of novel tumor-directed oncolytic immunotherapies. Replimune's proprietary RPx platform is based on a potent HSV-1 backbone with payloads added to maximize immunogenic cell death and the induction of a systemic anti-tumor immune response. The RPx platform has a unique dual local and systemic mechanism of action (MOA) consisting of direct selective virus-mediated killing of the tumor resulting in the release of tumor derived antigens and altering of the tumor microenvironment (TME) to ignite a strong and durable systemic response. This MOA is expected to be synergistic with most established and experimental cancer treatment modalities, and, with an attractive safety profile the RPx platform has the versatility to be developed alone or combined with a variety of other treatment options. 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 the design and advancement of our clinical trials, the timing and sufficiency of our clinical trial outcomes to support potential approval of any of our product candidates, our goals to develop and commercialize our product candidates, patient enrollments in our existing and planned clinical trials and the timing thereof, 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 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.

Investor Inquiries
Chris Brinzey
ICR Westwicke
339.970.2843
chris.brinzey@westwicke.com

Media Inquiries
Lissette Steele
Verge Scientific Communications
202.930.4762 x 409
lsteele@vergescientific.com

Replimune Group Inc