



Replimune Announces Initiation of the Phase 2 Portion of its Ongoing Phase 1/2 Clinical Trial of RP1 as Monotherapy and in Combination with Nivolumab

Trial in Progress Poster to be Presented Today at the 2019 American Society of Clinical Oncology Annual Meeting

WOBURN, Mass., June 01, 2019 (GLOBE NEWSWIRE) -- Replimune Group, Inc. (NASDAQ: REPL), a biotechnology company developing oncolytic immuno-gene therapies derived from its Immulytic™ platform, today announced that the Phase 2 portion of the Company's Phase 1/2 clinical trial of RP1 alone and in combination with nivolumab anti-PD1 therapy has initiated. In the Phase 2 portion of the clinical trial, RP1 in combination with nivolumab will be tested in four 30-patient cohorts of patients with melanoma, non-melanoma skin cancers (NMSC), metastatic bladder cancer or microsatellite instability-high (MSI-H) tumors. Enrollment is now open in the melanoma, NMSC and bladder cancer cohorts, and enrollment in the MSI-H cohort will open as soon as a protocol-required MSI-H patient is evaluable from Phase 1. The patients enrolled into the melanoma cohort either will be treatment naïve or have received one prior systemic therapy, and the patients enrolled into the other three cohorts will all be naïve to anti-PD1 therapy.

Data relating to the Phase 1 portion of the clinical trial, including biomarker data, is expected to be presented at a medical conference in the fourth quarter of 2019. The Phase 1 portion tested single agent RP1 by direct injection into a single superficial or nodal tumor and by imaging guided injection into a single visceral tumor in patients with advanced heavily pre-treated cancers who failed available therapy to define the recommended Phase 2 dose. Following determination of the recommended Phase 2 dose, an expansion group of advanced cancer patients who failed available therapy then received RP1 at the recommended Phase 2 dose in combination with nivolumab at standard clinical doses.

Poster Presentation at ASCO

The Company also announced that a trial in progress (TiP) poster will be presented today at the 2019 American Society of Clinical Oncology (ASCO) Annual Meeting currently being held in Chicago, IL. The poster describes the design and current status of the Phase 1/2 clinical trial, including the tumor types of the patients enrolled, and will be made available on the Company's website at the time of presentation.

Details of Replimune's poster presentation:

Abstract Title: An Open-Label, Multicenter, Phase 1/2 Study of RP1 as a Single Agent and in Combination with PD1 Blockade in Patients with Solid Tumors (Abstract TPS2671)

Session Title: Developmental Immunotherapy and Tumor Immunobiology

Session Date and Time: Saturday June 1st, 8:00am-11:00am CDT

Location: McCormick Place, Exhibit Hall A, Poster Board #301b

About RP1

RP1 is Replimune's first Immulytic™ product candidate to enter the clinic and is based on a proprietary new strain of herpes simplex virus engineered to maximize tumor killing potency, the immunogenicity of tumor cell death and the activation of a systemic anti-tumor immune response.

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. The Company'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. 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 use of cash, our advancement of our clinical trials, our goals to develop and commercialize our product candidates, our plans to establish our own in-house manufacturing capabilities, our proposed scientific presentations, 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 establishing, equipping, and operating our planned 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, and other risks set forth under the heading "Risk Factors" of our Quarterly Report on Form 10-Q for the third quarter ended December 31, 2018. 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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