Replimune Announces FDA Acceptance of Investigational New Drug Application for its Lead Oncolytic Immunotherapy Candidate, RP1

September 6, 2018

WOBURN, Mass., Sept. 06, 2018 (GLOBE NEWSWIRE) -- Replimune Group Inc. (NASDAQ: REPL), a biotechnology company developing oncolytic immunotherapies derived from its Immulytic™ platform, today announced theU.S. Food and Drug Administration (FDA) has accepted the Company's investigational new drug (IND) application for its lead product candidate, RP1, for patients with solid tumors. The Company intends to open its ongoing Phase 1/2 clinical trial in the U.S. and begin enrolling patients in the fourth quarter of 2018. The clinical trial is currently ongoing in the U.K., as previously announced.

In part one of the Phase 1/2 clinical trial, Replimune is assessing the safety and tolerability of RP1 administered alone in patients with advanced solid tumors. Following this dose escalation phase, further patients will receive RP1 in combination with nivolumab anti-PD1 therapy. In part two of the Phase 1/2 clinical trial, expected to initiate in the first half of 2019, Replimune intends to study the safety and efficacy of RP1 in combination with nivolumab in approximately 120 patients with metastatic melanoma, metastatic bladder cancer, microsatelite instability high cancers, and non-melanoma skin cancers. For each of the tumor types other than melanoma, patients will be naïve to immune checkpoint blockade, whereas in melanoma, patients both previously treated and previously untreated with immune checkpoint blockade will be enrolled. This clinical trial is a collaboration with Bristol Myers Squibb, which is providing nivolumab for use in the study.

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. This is intended to result in highly immunogenic cell death and robust activation of a systemic anti-tumor immune response.

About Oncolytic Immunotherapy
Oncolytic immunotherapy is an emerging class of cancer therapy which exploits the ability of viruses to selectively replicate in and kill tumors, while at the same time inducing a potent, patient-specific, anti-tumor immune response. Oncolytic viruses have the ability to induce a robust immune response against a patient's particular complement of tumor antigens, including neo-antigens, in situ in the patient in an off-the-shelf format. While clinically active alone, oncolytic immunotherapy may have synergy with certain other treatments and, in particular, with immune checkpoint blockade therapies.

About Replimune
Replimune Group, Inc, headquartered in Woburn, MA, was founded in 2015 to develop the next generation of 'oncolytic immunotherapies' 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 the timing and progress of our clinical development of our RP1 product candidate 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 obtain necessary funding, 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 first quarter ended June 30, 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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