Replimune Highlights Company Progress and Expected 2019 Milestones Ahead of Presentation at the 37th Annual JPMorgan Healthcare Conference

January 3, 2019

RP1: U.S. Enrollment Opened for Phase 1/2 Clinical Trial in Combination with Nivolumab in Patients with Solid Tumors

RP1: Randomized Controlled Phase 2 Clinical Trial Alone and in Combination with Cemiplimab On Track to Initiate H1 2019

RP2: Phase 1 Clinical Trial Alone and in Combination with Anti-PD1 Therapy On Track to Initiate H1 2019

RP3: Clinical Candidate Expressing Immune Co-Stimulatory Pathway Activating Ligands Selected

WOBURN, Mass., Jan. 03, 2019 (GLOBE NEWSWIRE) -- Replimune Group Inc. (NASDAQ: REPL), a biotechnology company developing oncolytic immuno-gene therapies derived from its Immulytic™ platform, today announced status updates highlighting progress with the Company's key programs.

"Replimune had a very productive 2018 with our successful initial public offering in July providing us with the funds to continue to advance our new generation of potentially best in class oncolytic immuno-gene therapies into and through clinical trials," said Robert Coffin, Ph.D., co-founder, President and CEO of Replimune. "We have made tremendous progress with all aspects of our business and are pleased that all programs continue to progress on track. We now look forward to 2019 when we expect to initiate enrollment of the Phase 2 portion of the Phase 1/2 clinical trial of RP1 in combination with nivolumab in four solid tumor types, initiate enrollment of our potentially pivotal randomized controlled Phase 2 clinical trial of RP1 in combination with cemiplimab in cutaneous squamous cell carcinoma (CSCC), and initiate clinical development of our RP2 product candidate expressing anti-CTLA-4."

Program Updates

- **RP1:**RP1 is Replimune's first product candidate to enter the clinic and is based on a proprietary new strain of herpes simplex virus armed with a gene encoding a potent fusogenic protein (GALV-GP-R-), intended to enhance tumor killing potency, immunogenic cell death and the activation of systemic anti-tumor immune responses, and with a gene encoding the cytokine GM-CSF. Replimune is currently testing RP1 in a two-part Phase 1/2 clinical trial in collaboration with Bristol Myers Squibb. 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 followed by dosing in combination with nivolumab anti-PD1 therapy. In part two of the Phase 1/2 clinical trial Replimune intends to study the safety and efficacy of RP1 in combination with nivolumab in four cohorts of patients with different solid tumor types. Replimune also intends to initiate a registration-directed randomized controlled Phase 2 clinical trial of approximately 240 patients with CSCC comparing treatment with cemiplimab alone to treatment in combination with RP1, under the Company's collaboration with Regeneron. Cemiplimab is Regeneron's anti-PD1 drug which was approved by the U.S. Food and Drug Administration (FDA) for the treatment of locally recurrent and metastatic CSCC in 2018.

Recent RP1-specific program progress is summarized below:

- Completed enrollment of RP1 alone in the Phase 1 portion of the Phase 1/2 study.
- Opened enrollment of the second part of the Phase 1 portion of the study, in which RP1 is being combined with nivolumab, in the United States (U.S.) and United Kingdom (UK).
  - Data from the full Phase 1 part of the Phase 1/2 study (RP1 alone and RP1 combined with nivolumab) is expected to be presented at a medical conference in the second half of 2019.
- On track to initiate the Phase 2 portion of the study in the first half of 2019 in four cohorts of approximately 30 patients each with melanoma, bladder cancer, microsatellite instability high cancers, and non-melanoma skin cancers.
- On track to initiate the registration-directed randomized, controlled Phase 2 clinical trial of RP1 in combination with cemiplimab in CSCC in the first half of 2019.

Pipeline product candidates (RP2 & RP3)

Replimune's pipeline product candidates are further armed versions of RP1 which focus on the delivery of immune activating genes to tumors which target clinically validated pathways that act as the immune response is initiated. In particular, these are pathways where Replimune believes systemic engagement may be sub-optimal.

- RP2 is a version of RP1 that, in addition to expressing GALV-GP-R and GM-CSF, also expresses a genetically encoded anti-CTLA-4 antibody intended to block the inhibition of the initiation of immune response caused by CTLA-4. RP2 is intended to be used primarily in combination with anti-PD-1 or anti-PD-L1 therapy.
    - The Company remains on track to initiate the clinical development of RP2 in a Phase 1 clinical trial of RP2 alone and in combination with anti-PD1 therapy in the first half of 2019.
- RP3 is a further armed oncolytic immuno-gene therapy which expresses two immune co-stimulatory activating ligands. Following the assessment of a number of co-stimulatory pathways, which like anti-CTLA-4 are expected to be primarily active at the site and time of anti-tumor immune response initiation, the selected RP3 product candidate to be moved forward to clinical development has now been finalized and will express CD40L and 4-1BBL, together with anti-CTLA-4 and GALV-GP-R-. CD40L activates CD40, resulting in the broad activation of both innate and adaptive immunity, and 4-1BBL activates 4-1BB (CD137) to promote the expansion of cellular and memory immune responses.
    - The Company remains on track to initiate the clinical development of RP3 in a Phase 1 clinical trial of RP3 alone and in combination with anti-PD1 therapy in the first half of 2020.

Cash Position: Based on its current operating plan, Replimune expects that its current cash, cash equivalents and short-term investments will enable it to fund its operating expenses and capital expenditure requirements into the second half of 2021.

JPMorgan Conference Presentation and Webcast

As previously announced, Replimune will be presenting at the 37th Annual JPMorgan Healthcare Conference on January 9 at 8:00am PT.

A simultaneous webcast will be available in the Investors section of Replimune's website at www.replimune.com. A replay will be available for 30 days following the conference.

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, 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 second quarter ended September 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.

Replimune Contact
Pamela Esposito, Ph.D.
Replimune Group Inc.
617.233.6988
pamela@replimune.com

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

Media Inquiries
Arleen Goldenberg
Verge Scientific Communications
917.548.1582
agoldenberg@vergescientific.com

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