Replimune Presents Initial Clinical Data with RP1 that Strongly Supports Expansion of Clinical Programs in Melanoma and Cutaneous Squamous Cell Carcinoma (CSCC)

November 8, 2019

Data demonstrate RP1 alone and combined with Opdivo® is well tolerated with anti-tumor efficacy in target tumor types

Mechanism of action confirmed for RP1 alone and in combination with Opdivo

Biomarker data suggests RP1 provides broad anti-tumor immune activation

WOBURN, Mass., Nov. 08, 2019 (GLOBE NEWSWIRE) -- Replimune Group, Inc. (NASDAQ: REPL), a biotechnology company developing oncolytic immuno-gene therapies derived from its Immulytic™ platform, will today present data from the Phase 1 part of its Phase 1/2 clinical trial of RP1 as monotherapy and in combination with Opdivo during a poster presentation at the 34th Annual Meeting of the Society for Immunotherapy of Cancer (SITC 2019) in National Harbor, Maryland (linked here). The Company has also separately released data from initial melanoma patients (linked here) and updated data from CSCC patients (linked here) treated in the Phase 2 part of the clinical trial.

As previously announced, an investor event will begin on November 8, 2019 at 6:30 p.m. ET to review this data. A link to the presentation can be found here and a simultaneous webcast will be available in the Investors and Media section of Replimune's website at www.replimune.com. A replay will be available for 30 days following the conference.

The data demonstrates that RP1 alone and in combination with Opdivo is well tolerated, with clear anti-tumor activity, and confirms the mechanism of action of RP1 alone and in combination with Opdivo. Based on the clinical activity seen, the Company is now planning a new clinical trial in melanoma patients who are refractory to anti-PD1 therapy, along with the previously announced expansion of its CSCC program to include a new clinical trial in solid organ transplant recipients.

"We are very pleased with the data showing that RP1 is well tolerated both alone and in combination with Opdivo, which was the primary objective of the Phase 1 part of the study," said Robert Coffin, Ph.D., President and CEO of Replimune. "In addition to being well tolerated, there was clear evidence of anti-tumor efficacy, particularly in the tumor types where further development of RP1 is focused, as well as strong biomarker data which indicates that broad immune activation was achieved. Based on the strength of this data, we intend to expand our clinical development program for RP1 to include a clinical trial of RP1 in combination with anti-PD1 therapy in melanoma patients who are refractory to treatment with anti-PD1 therapy."

The Phase 1 part of Replimune's Phase 1/2 clinical trial of RP1 enrolled 36 patients with advanced heavily pre-treated cancers who were refractory to available therapy. Treatment with RP1 alone was given up to five times at various dose levels injected into a single tumor to determine the recommended Phase 2 dose (N=22), following which RP1 was given up to eight times at the recommended dose in combination with Opdivo starting with the second dose of RP1 (N=14). Based on the data, which showed a favorable safety profile for both RP1 alone and in combination with Opdivo, the RP1 dosing regimen moved forward into Phase 2 development was an initial dose of up to 10mL of $1x10^6$ pfu/ml followed by subsequent doses of up to 10mL of $1x10^7$ pfu/ml.

In the dose rising monotherapy part of the Phase 1/2 clinical trial, RP1 was associated with tumor destruction, including delayed systemic post-study tumor reduction without further therapy. In the combination portion of the Phase 1 part of the clinical trial, anti-tumor activity was demonstrated in multiple patients with a variety of tumor types, particularly in CSCC and melanoma, but also in microsatellite instability high (MSI-H) colorectal cancer and esophageal cancer patients. Additionally, the first three of four patients with anti-CTLA-4 and anti-PD-1 refractory cutaneous melanoma treated with RP1 combined with Opdivo are responding to therapy (two patients from the Phase 1 part of the study and one from Phase 2) and clinical activity has been seen in four of the first five patients treated with CSCC. Of particular note, substantial tumor reduction was observed in a number of patients after just the first dose of RP1, but before the introduction of Opdivo two weeks later.

Biomarker data further confirmed the mechanism of action of RP1 alone and in combination with Opdivo, suggesting that RP1 provides broad anti-tumor immune activation. Increases in CD8 T Cells and PD-L1 were seen in serial tumor biopsies across tumor types, and the kinetics of virus detection suggests that robust virus replication in tumors occurs.

Continued recruitment of the Phase 2 part of the clinical trial in cohorts of 30 patients each with melanoma, non-melanoma skin cancers, bladder cancer, and MSI-H tumors is ongoing. Additional data from the Phase 2 part of the clinical trial is expected to be presented in 2020.

About RP1
RP1 is Replimune's lead Immulytic™ product candidate 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 advancement of our clinical trials, our plans to initiate new clinical trials, our goals to develop and commercialize our product candidates, 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 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.

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