Replimune Provides 2019 Year End Corporate Update and Reviews Expected 2020 Milestones

January 13, 2020

RP1: Registration-directed randomized controlled Phase 2 clinical trial of RP1 in combination with cemiplimab-rwlc (Libtayo®) in cutaneous squamous cell carcinoma (CSCC) underway

RP1: Study of RP1 as a monotherapy in solid organ transplant recipients with CSCC on track to initiate in H1 2020 with initial data expected by year-end

RP1: Additional Phase 2 readouts expected during 2020 in melanoma, non-melanoma skin cancers, bladder cancer and microsatellite instability-high (MSI-H) tumors

RP1: 125 patient Phase 2 cohort of RP1 combined with Opdivo® (nivolumab) in anti-PD-1 refractory melanoma on track to initiate in H1 2020

RP2: Phase 1 clinical trial of RP2 as monotherapy and in combination with Opdivo underway, with initial data expected in 2020

RP3: Phase 1 clinical trial of RP3 as monotherapy and in combination with an anti-PD-1 remains on track to initiate in 2020

WOBURN, Mass., Jan. 13, 2020 (GLOBE NEWSWIRE) -- Replimune Group Inc. (Nasdaq: REPL), a biotechnology company developing oncolytic immuno-gene therapies derived from its Immulytic™ platform, today provided a corporate update, highlighting the progress of its key programs.

“Replimune had a very productive 2019 where a key highlight included the presentation of initial clinical data with RP1 as monotherapy and combined with Opdivo at the 34th Annual Meeting of the Society for Immunotherapy of Cancer,” said Philip Astley-Sparke, Chief Executive Officer of Replimune. “We believe the data provides strong support for our ongoing registration-directed trial in our lead indication of CSCC as well as the decision to initiate a new clinical trial in organ transplant recipients who have developed the disease. Similarly, the data in melanoma led to the decision to expand the clinical trial to include a registration-directed cohort of melanoma patients who are refractory to prior treatment with anti-PD1 therapy. We also initiated our first clinical trial of RP2, the next therapy in our pipeline. Overall we are thrilled with our progress and are excited for the year ahead as we release further data sets, bring our third product into the clinic to address less immune-responsive tumors and as we continue to execute upon our mission to make our oncolytic immuno-gene therapies a cornerstone of cancer treatment.”

Program Updates

RP1: RP1 is Replimune’s first clinical product candidate 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. The Company presented initial data from the Phase 1/2 clinical trial of RP1 alone and in combination with Opdivo in November 2019 at SITC 2019. The Company believes the data demonstrates that RP1 used alone and in combination with Opdivo is well tolerated and showed preliminary anti-tumor efficacy in target tumor types providing strong support for its ongoing and planned development programs in melanoma and CSCC. This clinical trial is being conducted under a clinical trial collaboration and agreement with Bristol-Myers Squibb (BMS) for the supply of Opdivo.

Recent RP1-specific program progress is summarized below:

- The registration-directed Phase 2 clinical trial of RP1 in combination with Libtayo in CSCC is underway. This multi-center, randomized, controlled clinical trial is intended to enroll approximately 240 patients with CSCC. The clinical trial’s primary objective is to compare the response rate following treatment with RP1 in combination with Libtayo to the response rate achieved with Libtayo alone. Libtayo is an FDA-approved anti-PD-1 therapy developed by Regeneron and Sanofi for the treatment of patients with metastatic or locally-advanced CSCC who are not candidates for curative surgery or radiation. This clinical trial is being conducted under the Company’s collaboration agreement with Regeneron, whereby the Company and Regeneron split development and supply costs equally. Recruitment for this clinical trial is expected to take approximately 18 to 24 months and enroll patients in the United States, Australia, Canada, United Kingdom and European Union.

- Recruitment is currently ongoing in the Phase 2 part of the Phase 1/2 clinical trial of RP1 in combination with Opdivo. The Phase 2 part of the clinical trial is currently enrolling 30-patient cohorts with melanoma, non-melanoma skin cancers, metastatic bladder cancer, and MSI-H tumors. Data from completely enrolled or ongoing skin cancer cohorts is expected to be presented during the second half of 2020 with further data from all four cohorts expected to be available by year-end.

- On track to initiate a new registration-directed 125-patient cohort in the Phase 2 clinical trial of RP1 in combination with Opdivo in anti-PD-1 refractory melanoma patients in the first quarter of 2020, based on the initial clinical efficacy data with RP1 in melanoma. The additional cohort will be enrolled under an expansion of the clinical trial collaboration and Opdivo supply agreement with BMS.

- On track to initiate a clinical trial of RP1 as monotherapy in solid organ transplant recipients with CSCC in the first half of 2020. The U.S. Food and Drug Administration (FDA) has accepted the protocol for this clinical trial under its previously-accepted Investigational New Drug application for RP1. The clinical trial is intended to enroll approximately 30 patients and assess the safety and efficacy of RP1 in liver and kidney transplant recipients with recurrent CSCC and is expected to provide initial data by the end of 2020.

RP2: 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. Similar to RP1, RP2 is intended to be used primarily in combination with anti-PD-1 therapy.

- The Phase 1 clinical trial of RP2 alone and in combination with Opdivo is underway. The clinical trial is designed to assess the safety and tolerability, and to determine the optimal dose, of RP2 alone and in combination with Opdivo and is being conducted under a clinical trial collaboration and agreement with BMS for the supply of Opdivo. Initial data from this all-comers trial is expected by the end of 2020.

RP3: RP3 is a further armed oncolytic immuno-gene therapy which expresses two immune co-stimulatory activating ligands – CD40L and 4-1BBL – together with anti-CTLA-4 and GALV-GP-R-. CD40L activates CD40, which is intended to result in the broad activation of both innate and adaptive immunity, and 4-1BBL activates 4-1BB (CD137), which is intended to promote the expansion of cellular and memory immune responses.

- The Phase 1 clinical trial of RP3 alone and in combination with an anti-PD-1 therapy is expected to initiate in 2020.

Corporate Updates

- **Manufacturing:** Completed the build-out of Replimune's state of the art manufacturing facility to support late-stage development and commercialization. The 63,000-square-foot facility in Framingham, MA is intended to provide multi-product manufacturing capabilities for Replimune's Immulytic product candidates. The Company believes that the capacity of this facility is sufficient to support full commercialization of its product candidates. An occupancy certificate for the facility has been obtained and the first technology transfer manufacturing run has been successfully completed. Full GMP manufacturing is expected to commence in the first half of 2020.

- **Cash Position:** Based on its current operating plan, Replimune expects that its cash, cash equivalents and short-term investments, of approximately $183 million as of December 31, 2019, will be sufficient to fund its operating expenses and capital expenditure requirements into the second half of 2022.

J.P. Morgan Conference Presentation and Webcast.

As previously announced, the Company will be presenting at the 38th Annual J.P. Morgan Healthcare Conference on Tuesday, January 14th at 5:00 p.m. PT at the Westin St. Francis Hotel in San Francisco, CA. A simultaneous webcast of the presentation 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 cash runway, our advancement of our clinical trials, results of our clinical trials, our goals to develop and commercialize our product candidates, our plans to operate our own in-house manufacturing facility, our expectations with respect to our own in-house manufacturing capabilities, our proposed investor 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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