Replimune Provides 2020 Year End Review and Overview of Expected 2021 Milestones

January 11, 2021

RP1; Data in new indications expected in 2021 in anti-PD1 failed NSCLC, anti-PD1 failed CSCC and CSCC solid organ transplant recipient patients; further updates expected to be provided across all studies

RP2; New data to be reported in 2021 in combination with Opdivo in Phase 1 all comers study

RP3; First patient dosed; single agent data expected to be reported in 2021

Commercial-scale facility operational; GMP manufacturing underway

WOBURN, Mass., Jan. 11, 2021 (GLOBE NEWSWIRE) -- Replimune Group Inc. (NASDAQ: REPL), a biotechnology company developing oncolytic immuno-gene therapies derived from its Immulytic™ platform, provides corporate update, highlighting the progress of its key programs.

“Replimune made great progress in 2020 providing positive data read outs in multiple tumor types which support our registration-directed programs with RP1, as well as with RP2, demonstrating the potential of our platform to redefine the cancer treatment paradigm by providing what we believe to be the most practical and effective way to ignite a systemic immune response to a patient’s cancer. During the year we also completed the construction of and technology transfer to our state of the art commercial scale manufacturing facility” said Philip Astley-Sparke, Chief Executive Officer of Replimune. “We start this year with the recent news that dosing of patients has commenced with our third product candidate, RP3, which like RP2 is intended to treat tumor types which are not traditionally thought of as ‘immune-responsive’, and look forward to releasing further data on all of our programs during the course of 2021. We continue to enroll into our two registration-directed clinical trials in cutaneous squamous cell carcinoma (CSCC), the “CERPASS” study, and anti-PD1 failed melanoma, the “IGNYTE” study, and commercial planning activities are underway. We also expect to start dosing RP1 combined with Opdivo in anti-PD1 failed non-small cell lung cancer (NSCLC) patients and anti-PD1 failed CSCC patients this quarter. I am proud of the entire Replimune team for our accomplishments to date, as we continue to execute upon our mission to make oncolytic immuno-gene therapy a foundational cornerstone of cancer treatment.”

Program Highlights and Upcoming Milestones

- **RP1 in combination with Libtayo® in CSCC:** The Company is actively enrolling patients into its global registration-directed Phase 2, randomized, controlled, clinical trial. The Company remains on track to provide the primary data read out in 2022.

- **RP1 in combination with Opdivo® in anti-PD-1 failed melanoma:** The Company initiated recruitment into a new registration-directed 125-patient cohort Phase 2 clinical trial of RP1 in combination with Opdivo in the first half of 2020 and continues to enroll patients. The Company remains on track to provide the primary data readout in 2022.

- **RP1 in combination with Opdivo in melanoma and non-melanoma skin cancers (NMSC):** In October 2020, Replimune provided positive Phase 2 data updates in melanoma and NMSC which demonstrated deep and durable responses to RP1 combined with Opdivo, including in anti-PD1 failed melanoma that continues to support the Company’s ongoing registration-directed development in this setting and in CSCC. Enrollment of the initial melanoma cohort (including anti-PD1 naïve and anti-PD1 failed patients) was completed in the first half of 2020 with the NMSC cohort now being expanded from 30 to 45 patients to also include 15 patients with anti-PD1 failed disease.

- **RP1 in anti-PD1 failed NSCLC:** The Company has expanded the clinical study of RP1 combined with Opdivo to include a new cohort of 30 anti-PD1 failed NSCLC patients and plans to dose its first patient in early 2021.

- **RP1 as monotherapy in solid organ transplant recipients with CSCC:** The Company is currently enrolling a 30 patient Phase 1b clinical trial assessing the safety and efficacy of RP1 in liver and kidney transplant recipients. The Company expects to dose its first patient in early 2021. Progress on this study has been particularly impacted by COVID-19 due to the immune suppression that solid organ transplant patients receive. Initial data from this clinical trial is intended to be presented in the second half of 2021.

- **RP1 in combination with Opdivo in MSI-H/dMMR tumors:** The Company is accumulating data from the MSI-H/dMMR (anti-PD1 naïve) cohort. Based on the data, the Company expects to decide whether to pursue MSI-H/dMMR tumors into registration-directed development in 2021.

- **RP2 alone and in combination with Opdivo:** RP2 is an enhanced potency oncolytic immunotherapy which expresses an

anti-CTLA-4 molecule, intended to improve on the safety and efficacy profile of systemic antibody approaches to targeting CTLA-4, in addition to expressing the GALV-GP R- fusogenic protein and GM-CSF. RP2 is being evaluated in a Phase 1 clinical trial alone and combined with Opdivo in advanced solid tumor patients. In October 2020, Replimune presented positive data from the single agent RP2 portion of the clinical trial that showed deep and durable responses, including in patients with immune insensitive tumor types. Following the monotherapy phase, enrollment is currently underway in a 30-patient cohort in combination with Opdivo. Updated data from this clinical trial is expected to be presented mid-year.

- **RP3 alone and in combination with anti-PD-1 therapy:** Replimune initiated dosing in its Phase 1 clinical trial of RP3 in December 2020. RP3 is the Company's third product candidate, which in addition to GALV-GP R- and anti-CTLA-4 also expresses CD40L and 4-1BBL. The Phase 1 clinical trial is designed to evaluate RP3 alone and combined with anti-PD1 therapy in advanced solid tumor patients. Initial data is expected to be presented in the second half of 2021.

- **Targeted evaluation for new indications is currently underway:** An analysis of the solid tumor space is currently underway to define the later stage and registrational clinical development pathway initially intended for RP2 and/or RP3. This is from the perspective that RP2 and RP3 are intended to target less immune responsive tumor types, and follows from initial promising data having been generated with single agent RP2, including in immune non-responsive tumor types. The details of this initial development plan are intended to be announced mid-year.

Corporate Updates

- **Manufacturing:** The Company has completed buildout of its 63,000-square-foot state-of-the-art manufacturing facility in Framingham, MA to support late-stage development and full commercialization of all of its products. GMP production is underway.

- **Potential impact of COVID-19 on milestones:** Enrollment into the Company's clinical trials, in particular the clinical trial of RP1 in solid organ transplant patients with CSCC which represents a highly immune compromised patient population, has been slower than expected, which the Company attributes to the global pandemic. While mitigation plans have been implemented, as the clinical trial sites continue to evaluate their capacity to enroll patients into clinical trials, the Company could see additional impact on the pace of enrollment across its clinical trial programs.

- **Cash Position:** Based on its current operating plan, Replimune expects that its preliminary cash, cash equivalents and short-term investments of $493 million as of December 31, 2020 is expected to fund its operating expenses and capital expenditure requirements into the second half of 2024.

J.P. Morgan Conference Presentation and Webcast.

As previously announced, the Company will be virtually presenting at the 39th Annual J.P. Morgan Healthcare Conference on Tuesday, January 12th at 5:20 p.m. ET. 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. Replimune'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 across a broad range of cancers. 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, the advancement of our clinical trials, our plans to initiate new clinical trials, our goals to develop and commercialize our product candidates, patient enrollments in our existing and planned clinical trials and the timing thereof, the potential impact of COVID-19 on our operations and milestones, 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 operating our 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, political and global macro factors including the impact of the coronavirus as a global pandemic and related public health issues, 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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