Interim Results from the ARTACUS Clinical Trial of RP1 Monotherapy in Solid Organ and Hematopoietic Cell Transplant Recipients with Skin Cancers Presented During Oral Presentation at the American Association of Cancer Research (AACR) 2024 Annual Meeting

April 7, 2024

RP1 monotherapy showed clear anti-tumor activity with an overall response rate of nearly 35 percent and complete response rate of nearly 22 percent in evaluable patients

SAN DIEGO, April 07, 2024 (GLOBE NEWSWIRE) -- Replimune Group, Inc. (NASDAQ: REPL), a clinical stage biotechnology company pioneering the development of a novel portfolio of oncolytic immunotherapies, today announced the presentation of interim results from ARTACUS, a Phase 1/2 clinical trial evaluating RP1 monotherapy for the treatment of skin cancers in patients who have had solid organ or hematopoietic cell transplants, by Michael R. Midgen, M.D., of the University of Texas MD Anderson Cancer Center during an oral session at the AACR 2024 Annual Meeting in San Diego. The results were initially presented late last year at the 38th Annual Meeting of the Society for Immunotherapy of Cancer (SITC).

In the study, treatment with RP1 as monotherapy, for up to 25 doses, resulted in an overall response rate (ORR) of 34.8 percent (8 of 23 evaluable patients, including 5 complete responses and 3 partial responses) with most responses ongoing as of the data cutoff date of September 18, 2023. In the evaluable patient population (n=23), 20 had cutaneous squamous cell carcinoma (CSCC) and three had merkel cell carcinoma. Of note, a patient treated with RP1 for CSCC also had a complete response of a new primary basal cell carcinoma which appeared post baseline. There was no evidence of allograft rejection including of hepatic and lung allografts. RP1 monotherapy was well tolerated, and the safety profile was similar to the profile in non-immunocompromised patients with advanced skin cancers. Additional biomarker data collected showed an increase in CD+8 T, a type of immune cell, and an increase in the expression of PD-L1, after treatment suggesting immune activation. The slides are available on the Replimune website under presentations.

“Organ transplant recipients are at a higher risk for skin cancer when compared to the broader population and have access to a limited number of treatment options given that systemic immunotherapy is typically contra-indicated,” said Sushil Patel, Ph.D., CEO of Replimune. “These data show RP1 as monotherapy has clear anti-tumor activity and may be a safe and effective treatment option for these patients with an overall response rate of nearly 35 percent with good durability of benefit to date.”

About ARTACUS

ARTACUS is a multicenter, open-label, two-part Phase 1b/2 study evaluating RP1 as monotherapy for the treatment of locally advanced or metastatic cutaneous malignancies in patients who underwent a kidney, liver, heart, lung, or other solid organ transplant, or hematopoietic cell transplantation, who are on chronic immunosuppressive treatment, in whom systemic immunotherapy is typically contra-indicated. Researchers will assess the safety of RP1 and also evaluate its ability to shrink tumors. ARTACUS is currently recruiting patients. To learn more, contact clinicaltrials@replimune.com or +1-781-222-9570.

About RP1

RP1 is Replimune’s lead product candidate and is based on a proprietary new strain of herpes simplex virus engineered and genetically armed with a fusogenic protein (GALV-GP R-) and GM-CSF 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 with the mission to transform cancer treatment by pioneering the development of a novel portfolio of oncolytic immunotherapies. Replimune’s proprietary RPx platform is based on a potent HSV-1 backbone intended to maximize immunogenic cell death and the induction of a systemic anti-tumor immune response. The RPx platform is designed to have a unique dual local and systemic activity consisting of direct selective virus-mediated killing of the tumor resulting in the release of tumor derived antigens and altering of the tumor microenvironment to ignite a strong and durable systemic response. The RPx product candidates are expected to be synergistic with most established and experimental cancer treatment modalities, leading to the versatility to be developed alone or combined with a variety of other treatment options. 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 design and advancement of our clinical trials, the timing and sufficiency of our clinical trial outcomes to support potential approval of any of our product candidates, our goals to develop and commercialize our product candidates, patient enrollments in our existing and planned clinical trials and the timing thereof, 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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