Replimune Presents Initial RP1 Data from the ARTACUS Clinical Trial at the 2023 American Transplant Congress (ATC) Meeting

June 6, 2023

Single agent RP1 showed meaningful anti-tumor activity, with an overall response rate of 27.3% (all complete responses) in evaluable patients, with all responses ongoing to date

WOBURN, Mass., June 06, 2023 (GLOBE NEWSWIRE) -- Replimune Group, Inc. (NASDAQ: REPL), a clinical stage biotechnology company pioneering the development of a novel class of tumor-directed oncolytic immunotherapies, today announced initial data from ARTACUS, a Phase 1/2 trial evaluating RP1 for the treatment of cutaneous malignancies in patients who have had a kidney, liver, heart, lung, and/or a hematopoietic cell transplant. This data from the ARTACUS trial will be presented at the ATC 2023 Meeting being held in San Diego.

“Cutaneous cancer represents the most common post-transplant malignancy in highly immuno-compromised solid organ transplant patients. The challenge treating this high-risk population is that the use of anti-PD1 therapies can lead to organ transplant rejection in these patients,” said Robert Coffin, President and Chief Research & Development Officer of Replimune. “We are pleased with the interim data from the ARTACUS study that demonstrates a compelling overall response rate and complete response rate of 27.3% with strong durability to date that makes RP1 a potentially safe and effective treatment for these patients.”

Initial results from the Phase 1b/2 ARTACUS study of RP1 oncolytic immunotherapy in solid organ and hematopoietic cell transplant recipients with advanced cutaneous malignancies

ARTACUS is Replimune’s multicenter, open-label, 2-part Phase 1b/2 study evaluating RP1 for the treatment of locally advanced or metastatic cutaneous malignancies (to skin, soft tissue, or lymph nodes) in solid organ transplant recipients. This initial analysis includes kidney transplant recipients.

- This is the first clinical trial assessing single-agent RP1 in immunocompromised patients.
- No immune-mediated adverse events or evidence of allograft rejection were observed.
- RP1 monotherapy was well tolerated, and the safety profile was similar to non-immunocompromised patients with advanced skin cancers (IGNYTE study)
- RP1 monotherapy showed clear anti-tumor activity, with a preliminary overall response rate (ORR) for the 11 evaluable patients with cutaneous squamous cell carcinoma (N=10) and Merkel cell carcinoma (N=1) of 27.3%, with 3 patients (27.3%) achieving a confirmed complete response (CR). One of the non-evaluable patients also showed a clear reduction in tumor size before death due to COVID-19–related pneumonia at 7 weeks following initiation of RP1 (i.e. prior to the first formal efficacy assessment).

The poster is part of a poster session at ATC and can be found at Replimune’s website under Presentations.

- Presenter: Dr. Michael Migden
- Poster Session D – Transplant Oncology
- Presentation Time: Tuesday, June 6, 2023 from 9:45–10:25 AM PT and 3:00–3:30 PM PT

About ARTACUS
ARTACUS is Replimune’s Phase 1B/2 clinical trial to study the effects of the investigational oncolytic immunotherapy RP1 for the treatment of cutaneous malignancies in patients who underwent either a kidney, liver, heart, lung, or other solid organ transplant, or hematopoietic cell transplantation. Researchers will study the safety of this treatment in patients and also evaluate its ability to shrink tumors.

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 novel tumor-directed oncolytic immunotherapies. Replimune’s proprietary RPx platform is based on a potent HSV-1 backbone with

payloads added to maximize immunogenic cell death and the induction of a systemic anti-tumor immune response. The RPx platform has a unique dual local and systemic mechanism of action (MOA) consisting of direct selective virus-mediated killing of the tumor resulting in the release of tumor derived antigens and altering of the tumor microenvironment (TME) to ignite a strong and durable systemic response. This MOA is expected to be synergistic with most established and experimental cancer treatment modalities, and, with an attractive safety profile the RPx platform has 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.

Investor Inquiries
Chris Brinzey
Westwicke, an ICR Company
339.970.2843
chris.brinzey@westwicke.com

Media Inquiries
Arleen Goldenberg
Replimune
917.548.1582
media@replimune.com

Replimune Group Inc