Replimune Provides a Regulatory Update for its Registration- Directed Clinical Trials Evaluating RP1 in Combination with Libtayo® (cemiplimab) for the Treatment of CSCC & Evaluating RP1 in Combination with Opdivo® (nivolumab) in anti-PD1 Failed Melanoma

May 5, 2021

WOBURN, Mass., May 05, 2021 (GLOBE NEWSWIRE) -- Replimune Group, Inc. (Nasdaq: REPL), a biotechnology company developing oncolytic immuno-gene therapies derived from its Immulytic® platform, today announced a clinical development update for CERPASS, its registration-directed global randomized Phase 2 clinical trial of RP1 in combination with Libtayo® (cemiplimab) versus Libtayo for the treatment of cutaneous squamous cell carcinoma (CSCC), and for IGNYTE, its registration-directed single arm clinical trial in combination with Opdivo® (nivolumab) for the treatment of anti-PD1 failed melanoma.

CERPASS

“Based on the depth and durability of responses and the manageable safety profile we have seen in patients with non-melanoma skin cancers treated with RP1 in combination with Opdivo to date, we are amending the clinical trial protocol for our Phase 2 CERPASS clinical trial to include complete response (CR) rate as a primary endpoint in addition to overall response rate (ORR), and to reduce target enrollment to 180 patients,” said Robert Coffin, Ph.D., President and Chief Research and Development Officer of Replimune. “Incorporating CR as an independent additional primary endpoint should ensure a robust assessment of the clinical meaningfulness of adding RP1 to Libtayo in the primary data analysis upon which a BLA submission and FDA’s assessment for approval will be based.”

Under the modified clinical trial protocol for CERPASS, Replimune plans to add CR rate as an additional independent primary endpoint, in addition to ORR, and to reduce target enrollment from 240 patients to 180 patients. Secondary endpoints will continue to include duration of response, progression-free survival (PFS), and overall survival (OS). Replimune is maintaining its guidance to expect initial data in 2022.

Replimune plans to submit the amended CERPASS clinical trial protocol to the U.S. Food and Drug Administration (FDA) in the first half of the year.

Libtayo® is a registered trademark of Regeneron.

IGNYTE

Replimune recently held a Type B meeting with the FDA to discuss the design of the 125-patient, single-arm cohort in the IGNYTE clinical trial which is currently enrolling patients with anti-PD1 failed cutaneous melanoma, with registrational intent. The FDA expressed that while a randomized controlled trial would always be preferred to support licensure, that in this population if the data generated were sufficiently compelling, then the data could be considered for submission by the FDA under the accelerated approval pathway. The FDA also confirmed that a confirmatory trial would be needed as is required under the accelerated approval pathway. The design of the confirmatory trial is intended to be discussed with the FDA prior to a Biologics License Application (BLA) submission.

Dr. Coffin commented: “The discussion with the FDA at the Type B meeting provides clarity on the appropriate regulatory pathway to potential approval for RP1 in combination with Opdivo in anti-PD1 failed melanoma based on the data intended to be generated from our ongoing clinical trial. We look forward to releasing initial data from this study during 2022.”

Opdivo® is a registered trademark of Bristol Myers Squibb.

About CERPASS
CERPASS is Replimune’s registration-directed randomized, global Phase 2 clinical study to compare the effects of Libtayo alone versus a combination of Libtayo and Replimune’s investigational oncolytic immunotherapy RP1. The clinical trial will enroll 180 patients with locally advanced or metastatic cutaneous squamous cell carcinoma (CSCC) who are naïve to anti-PD1 therapy. The trial will evaluate complete response (CR) rate and objective response rate (ORR) as its two primary efficacy endpoints as assessed by independent review, as well as duration of response, progression-free survival (PFS), and overall survival (OS) as its secondary endpoints. The study is being run under a clinical trial collaboration agreement with Regeneron in which the costs of the trial are shared and full commercial rights retained by Replimune. Libtayo is being jointly developed by Regeneron and Sanofi.

About IGNYTE
IGNYTE is Replimune’s multi-cohort Phase 1/2 trial of RP1 plus Opdivo®. There are 4 tumor specific cohorts currently enrolling in this trial including a 125-patient extension cohort of RP1 combined with Opdivo in anti-PD-1 failed cutaneous melanoma. This cohort was initiated after completing enrollment in a prior Phase 2 cohort in the same trial of approximately 30 patients with melanoma. The additional thirty patient cohorts are studying RP1 in combination with Opdivo in non-melanoma skin cancers which

includes both naïve and anti-PD-1 failed CSCC, in microsatellite instability high, or MSI-H/dMMR tumor types and anti-PD-1 failed non-small cell lung cancer, or NSCLC. This trial is being done under a collaboration and supply agreement with Bristol Myer Squibb.

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 through the expression of a GALV-GP R- fusogenic protein and GM-CSF.

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 as well as in standalone indications. 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 the design and advancement of our clinical trials, the 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, 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.

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

Media Inquiries
Lissette Steele
Verge Scientific Communications
202.431.4116
lsteele@vergescientific.com