Replimune Presents Updated Data on RP2 in Uveal Melanoma during Plenary Session at the 20th International Congress of the Society for Melanoma Research

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RP2 as monotherapy and in combination with nivolumab showed a favorable safety profile and durable responses in nearly 30 percent of patients, all with previously treated disease

WOBURN, Mass., Nov. 08, 2023 (GLOBE NEWSWIRE) -- Replimune Group, Inc. (NASDAQ: REPL), a clinical stage biotechnology company pioneering the development of a novel portfolio of oncolytic immunotherapies, today announced updated data from a cohort of metastatic uveal melanoma patients enrolled in the open-label, multicenter, Phase 1 study of RP2 as a single agent and in combination with nivolumab. The data were presented by Dr. Joseph Sacco during a Plenary Session at the 20th International Congress of the Society for Melanoma Research in Philadelphia.

Treatment with RP2 led to an overall response rate (ORR) of 29.4 percent (5 of 17 patients; one of the responding patients was treated with RP2 monotherapy and four of the responding patients were treated with RP2 combined with nivolumab), including responses in patients with liver, lung, and bone metastases. The median duration of response (DOR) at the data cutoff was 11.47 months (range of 2.78 to 21.22 with responses ongoing). Nearly all patients (15 of 17, 88.2%) in the study had progressed on or after immunotherapy with 12 of 17 patients (70.6%) having received both prior anti-PD1 and anti-CTLA-4 therapy, including four of the responding patients. The slides are available on our website under presentations.

RP2 was generally well tolerated both as monotherapy and in combination with nivolumab with no additive adverse events observed. The most common grade 1 or 2 treatment related adverse events (TRAEs) overall in both cohorts were pyrexia, chills, fatigue, hypotension and pruritis. Six patients had grade 3 TRAEs, including two cases of hypotension. There were no grade 4 or 5 TRAEs.

“Metastatic uveal melanoma is an immunologically cold tumor type with few effective treatment options,” said Joseph Sacco, MBChB, PhD, FRCP, University of Liverpool and Clatterbridge Cancer Centre, UK. “In fact, single-agent and combination immune checkpoint inhibitor therapies, including ipilimumab combined with nivolumab, exhibit low response rates in patients with this disease, with combination therapies associated with significant toxicity. The data from this study are compelling given the rate of durable responses seen combined with a favorable safety profile, including in patients who had both liver and extra-hepatic metastases, further supporting the potential of RP2 in this patient population.”

Uveal melanoma is the most common form of intraocular primary malignancy and accounts for approximately 90 percent of all cases of ocular melanoma and up to 5 percent of all melanomas. Approximately 50 percent of patients will develop distant metastases, with about 90 percent of such patients manifesting liver metastases. Once the disease metastasizes, median overall survival is less than one year.

“These data from the trial cohort evaluating RP2 as monotherapy and in combination with nivolumab in metastatic uveal melanoma are highly promising,” said Robert Coffin, President and Chief Research & Development Officer at Replimune. “We are currently assessing the potential registrational path forward for RP2 in advanced uveal melanoma now that the Phase 1 development of RP2 in this disease is nearly complete. Metastatic uveal melanoma is a disease with significant unmet medical need where treatments remain limited, and no current standard of care options provide the potential for long term survival, other than in a minority of patients.”

About RP2

RP2 is a derivative of RP1, Replimune’s lead product candidate that 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. RP2 additionally expresses an anti-CTLA-4 antibody-like molecule, as well as GALV-GP-R- and GM-CSF. RP2 is intended to provide targeted and potent delivery of these proteins to the sites of immune response initiation in the tumor and draining lymph nodes, with the goal of focusing systemic-immune-based efficacy on tumors and limiting off-target toxicity.

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 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 to ignite a strong and durable systemic response. This MOA is 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 our expectations about our cash runway, 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, the availability of combination therapies needed to conduct our clinical trials, 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 the Russian-Ukrainian and Israel-Hamas political and military conflicts, 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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