Replimune Presents Positive Data from RP1 and RP2 Clinical Programs at the 2024 American Society of Clinical Oncology (ASCO) Annual Meeting

June 3, 2024

-- Investigator-assessed 12-month results from the IGNYTE clinical trial of RP1 plus nivolumab in anti-PD-1 failed melanoma demonstrate an overall response rate of 32.7% and duration of response consistent with the previously reported 6-month data from IGNYTE trial --

-- RP2 as monotherapy and in combination with nivolumab in uveal melanoma demonstrates overall response rate of nearly 30 percent; planning for registration-directed trial underway --

WOBURN, Mass., June 03, 2024 (GLOBE NEWSWIRE) -- Replimune Group, Inc. (NASDAQ: REPL), a clinical stage biotechnology company pioneering the development of a novel portfolio of oncolytic immunotherapies, today presented two oral presentations highlighting promising clinical data from its RP1 and RP2 programs at the 2024 American Society of Clinical Oncology (ASCO) Annual Meeting taking place May 31-June 4 in Chicago.

“The strength of the RP1 and RP2 data being presented at ASCO in two hard-to-treat tumor types further validates the potential of the RPx platform,” said Sushil Patel, Ph.D., CEO of Replimune. “In the IGNYTE trial, the investigator-assessed 12-month results show an overall response rate of 32.7% that was highly durable, and the combination provided a favorable safety profile, all consistent with previous data. The data with RP2 as monotherapy and in combination with nivolumab in refractory patients highlights a strong and durable overall response rate of nearly 30 percent in uveal melanoma where treatment options are limited.”

Key findings are outlined below.

Oral Presentation: Efficacy and Safety of RP1 Combined with Nivolumab in Patients with anti-PD-1-Failed Melanoma from the IGNYTE Clinical Trial (Session: Melanoma/Skin Cancers; June 3, 2024, 10:57AM CDT; **Location:** S406; **Abstract:** 9517)

- The data continues to show that the combination of RP1 and nivolumab in anti-PD-1 failed melanoma (n=156) provides deep and durable responses with an "on-target" safety profile with generally transient grade 1/2 adverse events, indicative of systemic immune activation.
- Approximately one third of patients experienced a response, with an overall response rate (ORR) by investigator assessment of 32.7%.
- In the 94 patients who had primary resistance to their immediate prior anti-PD-1 therapy, the ORR was 34%.
- In the 66 patients who progressed on prior anti-PD-1 combined with anti-CTLA-4 therapy, the ORR was 27.3%.
- All responses lasted greater than six months from enrollment, with a median duration of response exceeding 36 months.
- Clinically meaningful activity was observed across all enrolled subgroups, with over half of patients experiencing either a complete response (CR), partial response (PR) or stable disease (SD).

Primary analysis results by independent central review from the IGNYTE anti-PD-1 failed melanoma cohort are expected later in Q2 2024 with the Company on track to submit a biologics license application (BLA) for RP1 to the U.S. Food and Drug Administration (FDA) in 2H 2024. The Company also has agreed on a protocol for a Phase 3 confirmatory study with the FDA (IGNYTE-3; NCT06264180; poster TPS9603, ASCO 2024) and expects to initiate the trial prior to the RP1 BLA in anti-PD-1 failed melanoma being submitted.

“The findings shared for the IGNYTE clinical trial underscore the promising effects of RP1 shown to date, including overall response rate, durability and safety,” said Michael Wong, M.D., Ph.D., Professor of Melanoma Medical Oncology at The University of Texas MD Anderson Cancer Center and presenter of the study. “RP1 plus nivolumab provides an attractive risk-benefit profile for melanoma patients who have progressed on PD1 based treatment, particularly when compared with other therapies. For this population – the unmet need is significant as there are limited options with only about half of patients with melanoma responding to first line treatment.”

Oral Presentation: Safety, Efficacy, and Biomarker Results from an Open-Label, Multicenter, Phase 1 Study of RP2 Alone or Combined with Nivolumab in a Cohort of Patients with Uveal Melanoma (**Session:** Melanoma/Skin Cancers, June 3, 2024, 9:57AM CDT; **Location:** S406; **Abstract:** 9511)

- The data suggest that RP2, which expresses an anti-CTLA-4 antibody, dosed both alone and in combination with an anti-PD-1 agent in metastatic uveal melanoma patients (n=17), including those with both liver and extra-hepatic metastases, had a favorable safety profile and durable anti-tumor activity.
- RP2 administered as monotherapy or in combination with nivolumab demonstrated an ORR of 29.4%, with a disease control rate (DCR) of 58.8%.
- Biomarker data indicate immune cell infiltration and increased PD-L1 expression in tumors, together with changes in the systemic T cell repertoire following RP2 plus nivolumab.

- Based on the encouraging ORR observed amongst a patient population with historically poor treatment outcomes, Replimune is currently finalizing the protocol for a registration-directed study based on FDA input.

Both presentations will be available on the Company website under Events and Presentations.

About RP1
RP1 is Replimune's lead product candidate and is based on a proprietary strain of herpes simplex virus engineered and genetically armed with a fusogenic protein (GALV-GP-R-) and GM-CSF intended to maximize tumor killing potency, the immunogenicity of tumor cell death and the activation of a systemic anti-tumor immune response.

About RP2
RP2 is based on a proprietary strain of herpes simplex virus engineered and genetically armed with a fusogenic protein (GALV-GP-R-) and GM-CSF intended 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 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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