



Replimune Announces Positive Topline Primary Analysis Data by Independent Central Review from IGNYTE Clinical Trial of RP1 plus Nivolumab in Anti-PD1 Failed Melanoma

June 6, 2024

Primary endpoint data shows 12-month overall response rate (ORR) of 33.6%

Biologics license application (BLA) submission intended for 2H 2024; first patient expected to be enrolled in IGNYTE-3 confirmatory trial in Q3 2024

Company to host conference call and webcast today at 8:00 a.m. ET

WOBURN, Mass., June 06, 2024 (GLOBE NEWSWIRE) -- Replimune Group, Inc. (Nasdaq: REPL), a clinical stage biotechnology company pioneering the development of a novel class of oncolytic immunotherapies, today announced the topline results from the primary analysis of the IGNYTE clinical trial of RP1 plus nivolumab in anti-PD1 failed melanoma. The results by independent central review show one-third of patients receiving RP1 plus nivolumab responded to treatment, improving upon the investigator-assessed data presented at ASCO 2024, with all responses lasting greater than 6 months from baseline.

"The overall strength of the IGNYTE data and safety profile further highlights the potential of RP1 in a difficult treatment setting with limited options for patients," said Sushil Patel, Ph.D., CEO of Replimune. "Based on these compelling results and recent FDA interactions, we are increasingly confident in our path forward. We have shared the results with the agency and plan to request a pre-BLA meeting, in advance of our intended BLA submission. With these data in hand, we are preparing for a commercial launch next year."

The anti-PD1 failed melanoma cohort from the IGNYTE clinical trial includes 140 patients who received RP1 plus nivolumab after confirmed progression while being treated with at least 8 weeks of prior anti-PD1 therapy (+/- anti-CTLA-4). The primary analysis by independent central review was triggered once all patients had been followed for at least 12 months.

The topline results show the overall response rate was 33.6% by modified RECIST 1.1 criteria, the primary endpoint as defined in the protocol, and 32.9% by RECIST 1.1 criteria, an additional analysis requested by the FDA. Responses from baseline were highly durable, with all responses lasting more than 6 months and median duration of response exceeding 35 months. The Company plans to submit the full primary analysis data from the anti-PD1 failed melanoma cohort including key secondary endpoint data and subgroups for presentation at an upcoming medical congress.

RP1 combined with nivolumab continues to be well-tolerated, with mainly Grade 1-2 constitutional-type side effects, observed. Treatment-related adverse events associated with RP1 in combination with nivolumab were predominantly Grade 1-2 constitutional type events (> 5% of patients), including fatigue, chills, pyrexia, nausea, influenza-like illness, injection-site pain, diarrhea, vomiting, headache, pruritis, asthenia, arthralgia, myalgia, decreased appetite, and rash, with a low incidence of Grade 3-5 events. Grade 4 events were one each of lipase increased, alanine aminotransferase increased, blood bilirubin increased, cytokine release syndrome, myocarditis, hepatic cytolysis and splenic rupture. There were no Grade 5 events.

Conference Call Details

Replimune will host a conference call and webcast today at 8:00 a.m. ET. Listeners can register for the conference call via this [link](#). Analysts wishing to participate in the question-and-answer session should use this [link](#). The webcast and slides of the presentation can be accessed in the Investors section of the Company's website at www.replimune.com. A replay of the webcast will be available on the Company's investor website approximately two hours after the call's conclusion. Those who plan on participating are advised to join 15 minutes prior to the start time.

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 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 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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