Replimune Presents Primary Analysis Data from IGNYTE Clinical Trial of RP1 Combined with Nivolumab in Anti-PD1 Failed Melanoma at European Society for Medical Oncology (ESMO) Congress 2024

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Data from the IGNYTE primary analysis shows clinically meaningful activity across all subgroups, including those who had received prior anti-PD1 and anti-CTLA-4 or had primary resistance to anti-PD1

Injected and non-injected lesions responded with similar frequency, depth, duration and kinetics

WOBURN, Mass., Sept. 15, 2024 (GLOBE NEWSWIRE) -- Replimune Group, Inc. (NASDAQ: REPL), a clinical stage biotechnology company pioneering the development of novel oncolytic immunotherapies, today announced that data from the primary analysis of the IGNYTE clinical trial of RP1 combined with nivolumab were presented by Caroline Robert, M.D., Ph.D. of Gustave Roussy as a late breaking abstract during an oral session at the European Society for Medical Oncology (ESMO) Congress 2024 in Barcelona.

"We are excited to share the full IGNYTE primary analysis data which clearly shows clinically meaningful and durable systemic anti-tumor activity across the enrolled population, with responses in both injected and non-injected tumors, including visceral lesions," said Kostas Xynos, MD, PhD, MBA, Chief Medical Officer of Replimune. "These positive data will form the basis of our upcoming BLA submission for RP1 in anti-PD1 failed melanoma in the 2H 2024, which is an important step forward as we continue to progress RP1 plus nivolumab as a potential new option in a setting with only limited treatments currently available."

The anti-PD1 failed melanoma cohort from the IGNYTE clinical trial included 140 patients who received RP1 plus nivolumab after confirmed progression while being treated for at least 8 weeks with anti-PD1 based therapy (+/- anti-CTLA-4). The primary analysis by blinded independent central review was triggered once all patients had been followed for at least 12 months. Because of requirements that patients must have confirmed progressive disease on an immediate anti-PD1-based therapy, which is the current first line standard of care, most of the patients enrolled had 1 (45.7%) or 2 (18.6%) lines of prior therapies.

Results from the IGNYTE clinical trial presented at ESMO show:

- The overall response rate (ORR) was 33.6% by modified RECIST (mRECIST) 1.1 criteria, the primary endpoint as defined in the protocol, and 32.9% by RECIST 1.1 criteria, an additional sensitivity analysis requested by the FDA.
- The complete response rate by mRECIST was 15%.
- In patients who had prior anti-PD1 and anti-CTLA-4, the ORR was 27.7% and for those who had primary resistance to anti-PD1, the ORR was 35.9% by mRECIST.
- Median duration of response from response initiation was 21.6 months and media duration of response from treatment initiation was 27.6 months. At the time of the analysis, 85% of responses were ongoing more than a year from starting treatment.
- While median overall survival has not been reached, one-, two- and three-year survival rates were 75.3%, 63.3% and 54.8% respectively.

RP1 combined with nivolumab continues to be well-tolerated. 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 (12.8% of patients) of Grade 3-4 events, which were predominantly Grade 3. Grade 4 events were one each of lipase increased, cytokine release syndrome, myocarditis, hepatic cytolysis and splenic rupture. There were no Grade 5 events.

The presentation is available on the Company website under Events and Presentations.

About RP1
RP1 (vusolimogene oderparepvec) 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 novel 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, 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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