Replimune Highlights Acral Melanoma Data for RP1 plus Nivolumab at the ESMO Congress 2025

October 19, 2025

WOBURN, Mass., Oct. 19, 2025 (GLOBE NEWSWIRE) -- Replimune Group, Inc. (NASDAQ: REPL), a clinical stage biotechnology company pioneering the development of novel oncolytic immunotherapies, today announced data from a new ad hoc analysis from the IGNYTE phase 2 cohort of RP1 plus nivolumab was presented by Caroline Robert, M.D., Ph.D., at the European Society for Medical Oncology (ESMO) Congress 2025 being held in Berlin (Poster 1644P).

The analysis of acral melanoma patients from the IGNYTE clinical trial showed treatment with RP1 combined with nivolumab resulted in an objective response rate of 44% (8/18) with a median duration of response of 11.9 months (3.9, not reached). The safety profile was favorable with generally transient grade 1 and 2 treatment related adverse events.

Acral melanoma is a rare and aggressive type of cutaneous melanoma (2-3% of all melanoma cases) that frequently occurs on the palms of the hands, soles of the feet, and nailbeds, and often has poor outcomes with many patients presenting with in-transit metastases. Acral melanoma does not typically respond well to available therapies, such as immune checkpoint inhibitors. Following progression on first-line therapy, aside from targeted therapy for a subset of patients with BRAF mutation-positive tumors, few viable treatment options exist.

The IGNYTE-3 randomized controlled phase 3 trial evaluating RP1 plus nivolumab versus physician's choice of treatment in melanoma that has progressed on anti-PD1 and anti-CTLA-4 therapy is currently recruiting.

An additional poster titled, "Efficacy and safety of RP1 + nivolumab in patients with non-melanoma skin cancers (NMSC)" is also being presented at ESMO by Dirk Schadendorf, M.D. (Poster 1661P).

About IGNYTE
The IGNYTE phase 2 cohort enrolled 140 patients with stage IIIB-IV cutaneous melanoma and confirmed progression on anti-PD1- based therapy for > 8 weeks as the last prior treatment. RP1 was administered intratumorally into superficial and/or deep/visceral tumors once every 2 weeks for up to 8 doses (≤10 mL per cycle) with intravenous nivolumab (240 mg); nivolumab was then given alone (240 mg every 2 weeks or 480 mg every 4 weeks) for up to 2 years, with further RP1 allowed if indicated.

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 intended to ignite local 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 then activate 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 sufficiency of our clinical trials and outcomes, the potential applicability of our product candidates to treat certain indications, and other statements identified by words such as "could," "expects," "intends," "hope," "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 sufficient continuous operation of our in-house manufacturing facility to produce the necessary quality and quantity of our product candidates for continuous clinical trial supply, the timing and scope of regulatory approvals, if any, our ability to resolve the issues identified in the CRL and the Type A meeting in a manner satisfactory to the FDA and to us and the timing thereof, 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 a global pandemic and related public health issues and the ongoing political and military conflicts, including trade 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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