Replimune Presents Late-Breaking Abstract and Additional Posters on RP1 at 40th Annual Meeting of the Society for the Immunotherapy of Cancer (SITC 2025)

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Oral presentation of biomarker data shows RP1 plus nivolumab reverses multiple resistance mechanisms to PD-1 blockade in advanced melanoma following definitive anti-PD-1 failure

WOBURN, Mass., Nov. 07, 2025 (GLOBE NEWSWIRE) -- Replimune Group, Inc. (NASDAQ: REPL), a clinical stage biotechnology company pioneering the development of novel oncolytic immunotherapies, today announced that biomarker data and updated clinical data from the IGNYTE clinical trial of RP1 plus nivolumab was presented as a late-breaking abstract during an oral session at the 40th Annual Meeting of the Society for the Immunotherapy of Cancer (SITC 2025) in National Harbor, Maryland. Two additional posters on RP1 are also being presented.

"These data are important because they demonstrate that RP1 plus nivolumab can potentially reprogram the tumor microenvironment and reverse mechanisms of resistance to immune checkpoint blockade," said Kostas Xynos, M.D., Ph.D., Chief Medical Officer of Replimune. "Low T cell levels in tumors, tumor PD-L1 expression, T-cell activation and IFNy gene signature expression, as well as the loss of antigen presentation machinery are well known mechanisms of resistance to immune checkpoint blockade."

Data from the late-breaking abstract (#1327) presented by Trisha Wise-Draper, M.D., Ph.D., show:

- Pharmacodynamic changes that were not achieved during prolonged prior anti–PD-1 therapy demonstrate that the addition of RP1 reverses multiple resistance mechanisms to PD-1 blockade and highlights the contribution of RP1 in melanoma patients who previously failed such treatment.
- Treatment with RP1 plus nivolumab led to upregulation of gene signatures associated with responsiveness to PD-1 blockade.
- With additional follow-up (7 months), RP1 combined with nivolumab continues to demonstrate a clinically meaningful response rate (ORR: 33.6%) and durability (median duration of response: 24.8 months).
- Consistent duration of response was observed across PD-L1–positive and negative tumors, as well as in both primary and secondary resistance settings. Median duration of response for PD-L1-negative patients was 24.8 months and for patients with primary resistance was 22.6 months.

Additional posters being presented at the meeting include:

- **Abstract 611**: RP1 plus nivolumab in patients with and without prior BRAF-directed therapy: A subgroup analysis of patients with anti-PD-1 failed BRAF-mutant melanoma from the IGNYTE clinical trial (Katy Tsai, M.D.)
  - RP1 plus nivolumab demonstrated comparable efficacy in BRAF-mutant and BRAF–wild-type advanced melanoma.
  - Greater activity was observed in BRAF-naïve patients – similar to findings from the SECOMBIT and DREAMseq trials.
- **Abstract 600**: Retreatment with RP1 in combination with nivolumab in patients with advanced anti-PD-1- failed melanoma (Gino K. In, M.D.)
  - Extended RP1 treatment beyond 8 doses was well tolerated providing clinical benefit in a majority of patients.

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, the proposed mechanism of action of our product candidates and biologic effect, 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.

Investor Inquiries
Chris Brinzey
ICR Healthcare
339.970.2843
chris.brinzey@icrhealthcare.com

Media Inquiries
Arleen Goldenberg
Replimune
917.548.1582
media@replimune.com

Replimune, Inc.