Replimune Presents Final First-in-Human Data for RP2 in Advanced Solid Tumors During Oral Presentation at the 2026 American Society of Clinical Oncology Annual Meeting

May 31, 2026

WOBURN, Mass., May 31, 2026 (GLOBE NEWSWIRE) -- Replimune Group, Inc. (NASDAQ: REPL), a clinical-stage biotechnology company pioneering the development of novel oncolytic immunotherapies, today presented final first-in-human data for RP2 alone and in combination with nivolumab in patients with advanced solid tumors during an oral session at the 2026 American Society of Clinical Oncology annual meeting.

Key findings are detailed below.

Oral Presentation: RP2 oncolytic immunotherapy alone and in combination with nivolumab (nivo) in patients with advanced solid tumors: Final safety, efficacy, and biomarker results from the phase 1 first-in-human (FIH) study; **Date/Time**: May 31, 2026, 9:12 AM CDT; **Location**: Arie Crown Theater; **Abstract:** 2504; **Presenter**: Joseph Sacco, PhD, MBChB

- The Phase 1 first-in-human trial enrolled 85 heavily pretreated patients with advanced solid tumors, including uveal melanoma, colorectal cancer, head and neck cancers, pancreatic cancer, cutaneous melanoma, and sarcoma.
- Patients had received a median of 2 prior lines of systemic therapy; 42% had received prior immune checkpoint inhibitor (ICI) therapy
- RP2 monotherapy achieved an objective response rate (ORR) of 19.0% (4/21 evaluable patients), with responses observed in uveal melanoma, esophagogastric adenocarcinoma, chordoma, and mucoepidermoid carcinoma
- RP2 in combination with nivolumab achieved an ORR of 19.1% (9/47 evaluable patients), with a disease control rate of 48.9%
- In uveal melanoma, where a randomized Phase 2/3 trial is enrolling, the pooled ORR (RP2 in combination with nivolumab and RP2 monotherapy) was 33.3%
- Responses were durable: median duration of response was not reached in the monotherapy group (range: 11.5–27.3+ months) and was 22.1 months in the combination group (range: 2.8–35.2+ months)
- Tumor regression was observed in both injected and non-injected lesions, including in all 3 monotherapy responders who had non-injected lesions, demonstrating a systemic immune response beyond the site of injection
- Translational analyses demonstrated that RP2 reprogrammed tumors from immunologically "cold" to immune-inflamed, upregulated T-cell cytotoxicity and antigen presentation pathways, and significantly expanded HSV-1-specific and tumor-associated (MAGE) TCR clones, confirming the intended mechanism of action and systemic immune engagement.
- RP2 monotherapy and RP2 in combination with nivolumab were well tolerated with no unexpected toxicities, no Grade 4 or 5 treatment-related adverse events, and no increase in immune-related adverse events beyond the expected profile of nivolumab alone; the most common events were low-grade pyrexia, chills, and fatigue, consistent with systemic immune activation
- Based on these results, RP2 is being evaluated in combination with nivolumab in patients with metastatic uveal melanoma in a randomized Phase 2/3 trial (NCT06581406)

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 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 our expectations

about the status of the FDA review of our BLA for RP1 or potential approval of such BLA, 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, the regulatory review process and timing of potential product approval, 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 the outcome of FDA’s review process, 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 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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