Replimune Announces Favorable Outcome of FDA's Cellular, Tissue, and Gene Therapies Advisory Committee Meeting for RP1 in Advanced Melanoma

July 30, 2026

Advisory Committee voted 10 to 3 that the efficacy results from the IGNYTE study are evaluable and clinically meaningful

WOBURN, Mass., July 30, 2026 (GLOBE NEWSWIRE) -- Replimune Group, Inc. (Nasdaq: REPL), a clinical-stage biotechnology company pioneering the development of novel oncolytic immunotherapies, today announced the outcome of today's meeting of the U.S. Food and Drug Administration's (FDA) Cellular, Tissue, and Gene Therapies Advisory Committee (CTGTAC), which discussed the Biologics License Application (BLA) resubmission for RP1 (vusolimogene oderparepvec) in combination with nivolumab for the treatment of advanced melanoma in patients who have progressed on prior anti-PD-1 therapy.

The committee discussed two topics: (1) whether the single-arm IGNYTE study, as designed and conducted, allows for a reliable determination of the expected response rate and durability of response in the proposed population; and (2) the clinical meaningfulness of the response rate and duration of response reported in IGNYTE, and whether the observed responses are indicative of systemic antitumor activity attributable to RP1. The committee then voted 10 to 3, on the question: “Are the efficacy results from IGNYTE evaluable and clinically meaningful?”

“We are encouraged by today's outcome and would like to thank the committee for its thoughtful discussion of the IGNYTE data,” said Sushil Patel, Ph.D., CEO of Replimune. “We are grateful to the patients and physicians who took the time to speak today and so clearly articulate the high unmet need in advanced melanoma and importance of new treatment options such as RP1 for the community. This is an important step forward for patients with advanced melanoma who have progressed on anti-PD-1 therapy. We look forward to continuing to work with the FDA as it completes its review of the BLA ahead of the action date.”

The FDA's target action date under the Class 1 resubmission is August 2, 2026.

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 our expectations about the status of the advisory committee meeting being convened by the FDA, 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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