Replimune Announces Planned RP1 BLA Resubmission Following Productive Discussion with FDA

May 29, 2026

WOBURN, Mass., May 29, 2026 (GLOBE NEWSWIRE) -- Replimune Group, Inc. (NASDAQ: REPL), a clinical-stage biotechnology company pioneering the development of novel oncolytic immunotherapies, today announced that following collaborative communications with the U.S. Food and Drug Administration (FDA), the Company and the FDA have aligned on a path forward for resubmission and reconsideration of the Biologics License Application (BLA) for RP1 (vusolimogene oderparepvec) in combination with nivolumab for the treatment of advanced melanoma.

The company will resubmit the RP1 BLA in the coming days. The FDA has indicated it will treat the BLA resubmission as an urgent matter upon receipt and will prioritize its review in recognition of the significant unmet need for patients in the advanced melanoma community. This constructive dialogue represents an important step forward for the thousands of patients living with advanced melanoma who have progressed on prior anti-PD-1 based therapy and have limited treatment options available to them.

"We are grateful to the FDA leadership for their willingness to engage in a collaborative dialogue towards finding a meaningful path forward for RP1," said Sushil Patel, Ph.D., Chief Executive Officer of Replimune. "We are encouraged by the agency's commitment to supporting patients and U.S. innovation and look forward to working closely with the FDA to bring this important therapy to the advanced melanoma community as swiftly as possible."

The BLA is supported by data from the IGNYTE clinical trial, which evaluated RP1 combined with nivolumab in patients with confirmed progression on an anti-PD-1 containing regimen. Approximately 8,500 Americans with advanced melanoma die each year, and standard of care checkpoint inhibitor therapy fails approximately half of all patients who receive it, underscoring the urgent need for new treatment options.

About RP1
RP1 (vusolimogene oderparepvec) is Replimune's lead product candidate, based on a proprietary strain of herpes simplex virus engineered and genetically armed with a fusogenic protein (GALV-GP R^-) and GM-CSF. RP1 is designed to maximize tumor killing potency, the immunogenicity of tumor cell death, and the activation of a systemic anti-tumor immune response.

About Advanced Melanoma
Melanoma is the fifth most common cancer in the United States, with approximately 112,000 new cases estimated in 2026 and the most lethal form of skin cancer, accounting for nearly 8,500 deaths annually. Melanoma is considered advanced when the cancer has spread beyond the primary tumor. Standard of care therapy includes immune checkpoint blockade, to which approximately half of patients will not respond or will progress after treatment, leaving a significant population in need of effective therapeutic alternatives.

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.

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

Media Inquiries
Arleen Goldenberg
Replimune
917.548.1582
media@replimune.com