Replimune Announces FDA Acceptance of BLA Resubmission of RP1 for the Treatment of Advanced Melanoma

October 20, 2025

- Prescription Drug User Fee Act (PDUFA) target action date set for April 10, 2026 -

WOBURN, Mass., Oct. 20, 2025 (GLOBE NEWSWIRE) -- Replimune Group, Inc. (NASDAQ: REPL), a clinical stage biotechnology company pioneering the development of novel oncolytic immunotherapies, today announced that the U.S. Food and Drug Administration (FDA) has accepted the resubmission of the Biologics License Application (BLA) for RP1 in combination with nivolumab for the treatment of advanced melanoma in patients who progress on an anti-PD-1 containing regimen. The PDUFA date set by the FDA is April 10, 2026 based on a Class II resubmission timeline.

“We are pleased the agency has accepted the resubmission of our BLA for RP1,” said Sushil Patel, Ph.D., CEO of Replimune. “RP1 plus nivolumab offers a strong risk benefit profile where there are few options for patients with advanced melanoma, who have progressed on PD-1 based therapy. We look forward to working closely with the agency to expedite this review as much as possible for patients’ benefit.”

During the past few months, Replimune has been working to address agency feedback. Additional information, data and analyses were included in the resubmission which will be part of the BLA review. The FDA indicated this resubmission is considered to be a complete response to the complete response letter received in July 2025.

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, and regulatory filings with the FDA, the review and timing of our biologics license application by the FDA, 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.

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.