Replimune Announces Type A Meeting Scheduled with FDA

September 2, 2025

WOBURN, Mass., Sept. 02, 2025 (GLOBE NEWSWIRE) -- Replimune Group, Inc. (Nasdaq: REPL), a clinical stage biotechnology company pioneering the development of novel oncolytic immunotherapies, today announced that a Type A meeting with the U.S. Food and Drug Administration (FDA) has been scheduled to discuss the complete response letter (CRL) for the Company's Biologics License Application (BLA) for RP1 in combination with nivolumab for the treatment of advanced melanoma.

The Company submitted a briefing book to the FDA addressing the points from the CRL, highlighting prior agreements related to the patient population, criteria for PD-1 resistance, and use of literature to support contribution of components. The briefing book also includes an additional analysis of data from the BLA and addresses comments about the phase 3 confirmatory trial design.

"We are eager to engage in a productive discussion with the FDA to reach a swift resolution for the accelerated approval of RP1 in advanced melanoma," said Sushil Patel, Ph.D., CEO of Replimune. "The melanoma community, including leading physicians and patient advocacy groups have emphasized the urgent need for access to RP1 based on the strength of the data and limited effective treatment options for this population. We remain steadfastly committed to patient access while we work with the FDA to secure regulatory approval for RP1, however, without accelerated approval based on the current application, continuation of the RP1 program in advanced melanoma, including the phase 3 confirmatory trial, will not be viable."

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 our cash runway, the status of the FDA review or interactions following the complete response letter, 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 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

Replimune, Inc.