Replimune Receives Complete Response Letter from FDA for RP1 Biologics License Application for the Treatment of Advanced Melanoma

July 22, 2025

WOBURN, Mass., July 22, 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 issued a Complete Response Letter (CRL) regarding the Biologics License Application (BLA) for RP1 (vusolimogene oderparepvec) in combination with nivolumab for the treatment of advanced melanoma.

The CRL indicates that the FDA is unable to approve the application in its present form. The FDA has indicated that the IGNYTE trial is not considered to be an adequate and well-controlled clinical investigation that provides substantial evidence of effectiveness. Furthermore, the FDA said the trial cannot be adequately interpreted due to the heterogeneity of the patient population. The CRL also states that there are items related to the confirmatory trial study design which need to be addressed, including contribution of components. Importantly, no safety issues were raised.

The Company will request a Type A meeting and expects it will be granted within 30 days. Replimune plans to urgently interact with the FDA to find a path forward for the timely accelerated approval of RP1 without which the development of RP1 for advanced cancer patients with limited options will not be viable.

“We are surprised by this FDA decision and disappointed for advanced melanoma patients who have limited treatment options as highlighted by the granting of breakthrough status at the time we provided the IGNYTE primary data,” said Sushil Patel, Ph.D., Chief Executive Officer, Replimune. “The issues highlighted in the CRL were not raised by the agency during the mid- and late-cycle reviews. Additionally, we had also aligned on the design of the confirmatory study. We strongly believe that RP1 in combination with nivolumab can bring substantial benefit to advanced melanoma patients.”

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 designed to have a unique dual local and systemic 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 ignite 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 advancement of our clinical trials, the timing and sufficiency of our clinical trial outcomes to support potential approval of any of our product candidates, 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 the coronavirus as a global pandemic and related public health issues and the Russian-Ukrainian and Israel-Hamas political and military 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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