Replimune Receives Breakthrough Therapy Designation for RP1 and Submits RP1 Biologics License Application to the FDA under the Accelerated Approval Pathway

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WOBURN, Mass., Nov. 21, 2024 (GLOBE NEWSWIRE) -- Replimune Group, Inc. (NASDAQ: REPL), a clinical stage biotechnology company pioneering the development of novel oncolytic immunotherapies, today announced that it has submitted a biologics license application (BLA) to the FDA for RP1 (vusolimogene oderparepvec) in combination with nivolumab for the treatment of adult patients with advanced melanoma who have previously received an anti-PD1 containing regimen. The submission was made under the Accelerated Approval pathway. The Company also announced that the FDA has granted Breakthrough Therapy designation to RP1 in combination with nivolumab in the same setting.

Breakthrough Therapy designation is intended to expedite the development and review of therapies for serious diseases when preliminary clinical evidence indicates that the therapy may provide substantial improvement over existing available therapies on one or more clinically significant endpoints. This Breakthrough Therapy designation is based on the safety and clinical activity observed in the anti-PD1 failed melanoma cohort of the IGNYTE clinical trial.

“Today is an important milestone for Replimune and for the melanoma community as we are one step closer to having another potential treatment available for patients who have limited options after progressing on anti-PD1 containing regimens,” said Sushil Patel, Ph.D., CEO of Replimune.

The confirmatory Phase 3 IGNYTE-3 trial of RP1 in combination with nivolumab in advanced melanoma patients who have progressed on anti-PD1 and anti-CTLA-4 therapy, or who are not candidates for anti-CTLA-4 treatment is currently enrolling patients. For more information, visit https://replimune.com/clinical-trials/ignyte-3/.

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 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 our belief regarding the effect that the breakthrough designation will have on the timing and development of RP1 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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