Replimune Announces First Patient Dosed in IGNYTE-3 Clinical Trial in Advanced Melanoma

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Confirmatory Phase 3 Trial to assess efficacy and safety of the investigational oncolytic immunotherapy, RP1 (vusolimogene oderparepvec) in combination with nivolumab in patients with advanced melanoma

WOBURN, Mass., Aug. 13, 2024 (GLOBE NEWSWIRE) -- Replimune Group, Inc. (NASDAQ: REPL), a clinical stage biotechnology company pioneering the development of a novel class of oncolytic immunotherapies, today announced that the first patient has been randomized and dosed in the IGNYTE-3 study – a global Phase 3 clinical trial assessing the efficacy and safety of RP1 (vusolimogene oderparepvec) plus nivolumab in patients with advanced melanoma who have progressed on anti-PD1 and anti-CTLA-4 drugs or are ineligible for anti-CTLA-4 treatment.

“The start of the IGNYTE-3 trial and randomization of the first patient is an important milestone in advance of our planned BLA submission of RP1 in advanced melanoma later this year,” said Kostas Xynos, MD, PhD, MBA, Chief Medical Officer at Replimune. “This trial is important because it is intended to both support global regulatory interactions and access, and to serve to confirm the clinical benefit reported from the registration intended Phase 2 IGNYTE cohort in anti-PD1 failed melanoma in June.”

Melanoma is the fifth most common cancer with approximately 100,000 new cases and 8,000 deaths estimated in the U.S. in 2024. Standard of care therapy includes treatment with immune checkpoint blockade, to which approximately half of patients will not respond or will progress following treatment. Treatment options are limited after immune checkpoint blockade therapy, with no standard of care available to patients.

“Clinical trials like IGNYTE-3 are important in the melanoma community and we are excited that another study is open for physicians and patients to consider,” said Kyleigh LiPira, CEO of the Melanoma Research Foundation. “As a patient advocacy organization, our mission is to eradicate melanoma by accelerating medical research while educating to and advocating for the melanoma community. Creating awareness for clinical trials is an important part of that mission.”

The IGNYTE-3 trial (NCT06264180) will enroll 400 patients and evaluate RP1 plus nivolumab versus a defined list of physician’s choice treatment options, in patients with advanced melanoma who progressed on anti-PD1 and anti-CTLA-4 therapy or who are ineligible for anti-CTLA-4 treatment. The primary endpoint of the study is overall survival (OS). Key secondary endpoints are progression free survival (PFS) and objective response rate (ORR). For additional information about the IGNYTE-3 trial and to learn more about eligibility, please 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 a novel portfolio of 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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