Replimune Announces RP2 Development Program Advances with First Patients Enrolled in Metastatic Uveal Melanoma and Hepatocellular Carcinoma Clinical Trials

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WOBURN, Mass., Jan. 08, 2025 (GLOBE NEWSWIRE) -- Replimune Group, Inc. (NASDAQ: REPL), a clinical stage biotechnology company pioneering the development of novel oncolytic immunotherapies, today announced that the first patients have been enrolled in studies evaluating RP2 in two different settings: checkpoint naïve metastatic uveal melanoma; and second-line recurrent or metastatic hepatocellular carcinoma (HCC).

“On the heels of our BLA submission for RP1 and designation as breakthrough therapy, we are pleased that the first patients have been enrolled in both the RP2 HCC clinical trial and the registration intended study of RP2 in metastatic uveal melanoma,” said Sushil Patel, Ph.D., CEO of Replimune. “We are excited to explore the broader potential of the RPx platform and these RP2 clinical trials will play an important part of our future development plans.”

RP2-202 Clinical Trial in Metastatic Uveal Melanoma
Uveal melanoma is a type of cancer that occurs in the tissues of the eye. Up to 50 percent of patients with uveal melanoma may develop metastatic disease. The most common site of metastasis for uveal melanoma is the liver and is estimated to occur in 90-95% of cases.[1]

“We are honored and excited to be able to offer this clinical trial to our patients with uveal melanoma, a group of patients for whom treatment options are very limited,” said Dr. Justin Moser, an associate clinical investigator in the Cancer Research Division of HonorHealth Research Institute, where he specializes in uveal melanoma. “We hope that, by providing our patients with early access to treatments through clinical trials, that we will be able to help give them longer, higher-quality lives.”

During ASCO 2024, results from an open-label, multicenter, Phase 2 study of RP2 alone or combined with nivolumab in a cohort of patients with uveal melanoma (n=17) were presented. RP2 administered as monotherapy or in combination with nivolumab demonstrated an overall response rate of 29.4%, with a disease control rate of 58.8%.

The RP2-202 trial (NCT06581406) is a randomized, phase 2/3 study that will enroll approximately 280 patients and evaluate RP2 in combination with nivolumab versus ipilimumab in combination with nivolumab in immune checkpoint inhibitor-naïve adult patients with metastatic uveal melanoma. The primary endpoints of the study are overall survival and progression free survival. Key secondary endpoints are overall response rate and disease control rate. For additional information about the RP2-202 clinical trial and to learn more about eligibility, please visit our clinical trials page here.

RP2-003 Clinical Trial in Hepatocellular Carcinoma
HCC is the third leading cause of cancer-related deaths in the world. Prognosis is generally poor with the majority of HCC cases diagnosed in the advanced stage. HCC comprises approximately 75 to 85 percent of primary liver cancer cases.

The RP2-003 trial (NCT05733598) is an open label trial that will enroll 30 patients and evaluate RP2 combined with the second-line therapy of atezolizumab and bevacizumab in patients with locally advanced unresectable, recurrent and/or metastatic HCC. The primary endpoint of the study is overall response rate (ORR) per modified RECIST 1.1 criteria. Key secondary endpoints are ORR per RECIST modified for HCC and duration of response. The study is being conducted under a collaboration and supply agreement with Roche. For additional information about the RP2-003 trial and to learn more about eligibility, please visit our clinical trials page here.

About RP2
RP2 is a derivative of RP1, Replimune’s lead product candidate that is based on a proprietary new strain of herpes simplex virus engineered and genetically armed with a fusogenic protein (GALV-GP R-) and GM-CSF to maximize tumor killing potency, the immunogenicity of tumor cell death and the activation of a systemic anti-tumor immune response. RP2 additionally expresses an anti-CTLA-4 antibody-like molecule, as well as GALV-GP-R- and GM-CSF. RP2 is intended to provide targeted and potent delivery of these proteins to the sites of immune response initiation in the tumor and draining lymph nodes, with the goal of focusing systemic-immune-based efficacy on tumors and limiting off-target toxicity.

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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[1] Carvajal RD, Schwartz GK, Tezel T, Marr B, Francis JH, Nathan PD. Metastatic disease from uveal melanoma: treatment options and future prospects. Br J Ophthalmol. 2017 Jan;101(1):38-44. doi: 10.1136/bjophthalmol-2016-309034. Epub 2016 Aug 29. PMID: 27574175; PMCID: PMC5256122.

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