Replimune Announces First Patient Enrolled in Phase 1 Clinical Trial of RP2 Alone and in Combination with Opdivo® in Advanced Cancer Patients

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Replimune's second product candidate to enter the clinic is an Immulytic™ that expresses an anti-CTLA-4 antibody-like protein

WOBURN, Mass., Oct. 24, 2019 (GLOBE NEWSWIRE) -- Replimune Group Inc. (NASDAQ: REPL), a biotechnology company developing oncolytic immuno-gene therapies derived from its Immulytic platform, today announced that the company has enrolled the first patient in its Phase 1 clinical trial of RP2. RP2 expresses a genetically encoded anti-CTLA-4 antibody-like molecule, in addition to GALV-GP-R- and GM-CSF, both of which are expressed in Replimune's first product candidate, RP1. This is intended to block the inhibition of the initiation of immune responses caused by CTLA-4.

"We are excited to be advancing RP2, our second novel Immulytic product candidate, into clinical studies," said Robert Coffin, Ph.D., co-founder, President and CEO of Replimune. "CTLA-4 inhibition is an established mechanism of action for cancer treatment, including proven synergy with anti-PD1 therapy. By combining the expression of anti-CTLA-4 with oncolytic tumor destruction and antigen release directly in the tumor and draining lymph nodes, we believe that the efficacy of CTLA-4 inhibition can be enhanced with RP2, while reducing toxicity as compared to systemic administration."

The Phase 1 clinical trial will study RP2 as a single agent and in combination with Opdivo (nivolumab) in patients with advanced solid tumors. The Phase 1 clinical trial is designed to assess the safety, tolerability and to determine the optimal dose of RP2 alone and in combination with anti-PD1 therapy and is being conducted as a collaboration with Bristol-Myers Squibb Company (BMS). BMS has granted Replimune a nonexclusive, non-transferable, royalty-free license to, and will supply at no cost, Opdivo®, for use in combination with RP2. BMS has no further development-related obligations under this collaboration.

About RP2

RP2 is Replimune's second Immulytic product candidate and like RP1, is based on a proprietary new strain of herpes simplex virus which expresses GM-CSF and the fusogenic protein GALV-GP R-. In addition to the properties of RP1, RP2 expresses an anti-CTLA-4 antibody-like protein in order to block the inhibition of the immune response otherwise caused by CTLA-4. In preclinical studies comparing RP1 to RP2 to determine the effect of expressing anti-CTLA-4, RP2 demonstrated enhanced efficacy both alone and in combination with anti-PD1 therapy both in tumors which were injected with RP1 or RP2 and in tumors which were left uninjected.

About Replimune

Replimune Group Inc., headquartered in Woburn, MA, was founded in 2015 to develop the next generation of "oncolytic immune-gene therapies" for the treatment of cancer. Replimune is developing novel, proprietary therapeutics intended to improve the direct cancer-killing effects of selective virus replication and the potency of the immune response to the tumor antigens released. The Company's Immulytic platform is designed to maximize systemic immune activation, in particular to tumor neoantigens, through robust viral-mediated immunogenic tumor cell killing and the delivery of optimal combinations of immune-activating proteins to the tumor and draining lymph nodes. The approach is expected to be highly synergistic with immune checkpoint blockade and other approaches to cancer treatment. Replimune intends to progress these therapies rapidly through clinical development in combination with other immuno-oncology products with complementary mechanisms of action. For more information, please visit www.replimune.com.

Opdivo is a registered trademark of Bristol-Myers Squibb Company.

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 advancement of our clinical trials and product candidates, our goals to develop and commercialize our product candidates 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 establishing, equipping, and operating our planned in-house manufacturing facility, the timing and scope of regulatory approvals, changes in laws and regulations to which we are subject, competitive pressures, our ability to identify additional product candidates, 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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