Replimune Announces First Patient Dosed with RP3 in a Phase 1 Clinical Trial in Patients with Advanced Solid Tumors

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WOBURN, Mass., Jan. 05, 2021 (GLOBE NEWSWIRE) -- Replimune Group, Inc. (NASDAQ: REPL), a biotechnology company developing oncolytic immuno-gene therapies derived from its Immulytic™ platform, announced it has dosed the first patient in a Phase 1, open-label, dose-escalation and expansion clinical trial of RP3 both alone and in combination with anti-PD-1 therapy. RP3, Replimune's third product candidate to enter clinical development, encodes for CD40L and 4-1BBL in addition to the GALV-GP R(-) fusogenic protein encoded in RP1 and the anti-CTLA-4 molecule encoded in RP2. Expression of CD40L and 4-1BBL are intended to further stimulate an anti-tumor immune response through immune co-stimulatory pathway activation.

Replimune's product candidates are designed to comprehensively activate an anti-tumor immune response to a patient's cancer through the delivery of potent immune activating signals into the tumor, such that each of the stages of immune activation are maximized. The signals provided are (i) potent antigen release and presentation, so-called immunologic "Signal 1", provided by robust tumor destruction and immunogenic cell death through the use of the high potency oncolytic backbone expressing the GALV-GP R- fusogenic protein in all of our product candidates; (ii) the inhibition of signals which block full immune activation, provided by expression of anti-CTLA-4 in both RP2 and RP3; (iii) provision of potent immune co-stimulatory signals, so-called immunologic "Signal 2", provided by expression of CD40L and 4-1BBL in RP3; and (iv) the production of inflammatory cytokines, so-called immunologic "Signal 3", also intended to be stimulated by the expression of CD40L and 4-1BBL in RP3. RP3 therefore represents the culmination of this approach to date, and is intended to build on the compelling clinical data generated with RP1 and RP2, including in immune non-responsive tumor types.

"We are pleased to be advancing our third oncolytic immune-gene therapy into the clinic," said Robert Coffin, PhD, Founder, President and Chief Research & Development Officer of Replimune. "Having demonstrated the potential of our platform through positive clinical data readouts with both RP1 and RP2 in multiple tumor types, we have armed RP3 to express additional immune-activating proteins intended to further enhance the ability of our product candidates to treat less immune-responsive tumor types. We believe that the combined properties of RP3 are unique in the field of immune oncology and demonstrate the power of our platform to generate product candidates with multiple mechanisms of action which together potently activate a patient's immune system against their cancer. We look forward to providing initial data with RP3, along with our other clinical programs over the course of 2021."

The Phase 1, dose-escalation clinical trial is currently enrolling patients with advanced solid tumors. The clinical trial is primarily designed to assess safety and tolerability of RP3 and to determine the recommended Phase 2 dose. Following dose selection, the second part of the clinical trial is intended to dose patients with RP3 in combination with anti-PD1 therapy to further assess for both safety and initial efficacy.

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. Replimune'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 across a broad range of cancers. 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.

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 expectations about the advancement of our clinical trials, the timing of the release of clinical data for RP3 and other product candidates, our intention to initiate an expansion portion of our clinical trial of RP3 in combination with anti-PD1 therapy 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, 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 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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