Replimune Provides Updated Data from RP2 at the 2021 Society for Immunotherapy of Cancer's (SITC) 36th Annual Meeting

November 12, 2021

RP2 data demonstrates deep and durable responses in difficult to treat cancers both as monotherapy and in combination with Opdivo® (nivolumab)

Initiated Phase 1 expansion of RP2 in combination with Opdivo focused on patients with liver metastases

WOBURN, Mass., Nov. 12, 2021 (GLOBE NEWSWIRE) -- Replimune Group, Inc. (Nasdaq: REPL), a biotechnology company developing oncolytic immuno-gene therapies derived from its Immulytic™ platform, today announced updated interim data from the Phase 1 data from RP2 alone and in combination with Opdivo that continues to provide strong support for the next stage development of RP2. The poster will be presented November 12-14, 2021 at 7:00 a.m. ET to 5:00 p.m. ET at the Society for Immunotherapy of Cancer's (SITC) 36th Annual Meeting being held November 10-14, 2021.

Updated RP2 data shows compelling durability of response as single agent and in combination with Opdivo providing additional evidence of the clinical utility of RP2 in patients with hard-to-treat, anti-PD1 failed cancers.

RP2 leverages Replimune's platform to express an anti-CTLA-4 antibody, in addition to GALV-GP R- and GM-CSF which is expressed by RP1. The Company has now fully enrolled the 30-patient cohort evaluating RP2 combined with Opdivo following previously completing enrolment of the 9-patient cohort evaluating RP2 as monotherapy. The Phase 1 clinical trial population comprised patients with advanced cancers having failed, or being ineligible for, standard of care options.

The updated interim data shows:

- In the nine-patient monotherapy cohort with RP2, two of the initial three patients who achieved response remain in response, these being a patient with esophageal cancer (partial response; previously anti-PDL1 failed) at 22 months from entering the trial and a patient with mucoepidermoid carcinoma (complete response) at 19 months from entering the trial. As previously reported, the third responding patient with uveal melanoma with a partial response (Yervoy/Opdivo failed) progressed at 15 months from entering the trial.
- Updated data from the 30-patient cohort of RP2 in combination with Opdivo shows durable responses ongoing at out to >425 days.
- To date, seven of the 30 patient (23.3%) cohort of RP2 in combination with Opdivo have achieved partial responses, with additional patients still on study with the opportunity to achieve a response. Six of the seven responses are ongoing with depth of response having been maintained or deepened over time.
- The responding patients are four of nine patients with cutaneous melanoma (all anti-PD1 or anti-PD1 and anti-CTLA-4 failed), two of eight patients with uveal melanoma (anti-PD1 or anti-PD1 and anti-CTLA-4 failed) and one of three patients with squamous cell carcinoma of the head and neck (anti-PD1 failed).
- Biomarker data continues to demonstrate substantial increases CD8 T cells and PD-L1 expression, with T cell receptor sequencing and Nanostring expression analysis further indicating potent and broad activation of an anti-tumor immune response.
- No correlation has been observed between the degree of anti-tumor response and the baseline levels of PD-L1 expression, in line with the intended mechanism of action for RP2 of turning immunologically 'cold' tumors 'hot'.
- Overall the data, including the durability of the responses, continues to support that oncolytic immunotherapy-mediated expression of anti-CTLA-4 from RP2 provides potent & systemic anti-tumor effects, without substantial additional toxicity as compared to the oncolytic backbone (RP1), including without evidence of the side effects associated with systemic ipilimumab.
- Based on the observation of durable clinical responses in patients with liver metastases following treatment with both RP1 and RP2, the Company has amended the clinical trial protocol to enrol an additional 24 patients with liver metastases from lung cancer, gastrointestinal cancers, breast cancer and uveal melanoma.

Replimune will also be presenting three additional Trial in Progress presentations at this year's SITC Annual Meeting

Abstract Title: ARTACUS: An open-label, multicenter, phase 1b/2 study of RP1 in solid organ transplant recipients with advanced cutaneous malignancies (Trial in Progress presentation)
Abstract Number: 550
Session Date and Time: November 12-14, 2021 from 7:00 AM ET- 5:00 PM ET
Location: Hall E

Abstract Title: CERPASS: A randomized, controlled, open-label, phase 2 study of cemiplimab ± RP1 in patients with advanced cutaneous squamous cell carcinoma (Trial in Progress presentation)
Abstract Number: 547

Session Date and Time: November 12-14, 2021 from 7:00 AM ET- 5:00 PM ET
Location: Hall E

Abstract Title: IGNYTE: An open-label, multicenter, phase 1/2 (Ph 1/2) clinical trial of RP1 ± nivolumab in patients with advanced solid tumors (Trial in Progress presentation)
Abstract Number: 506
Session Date and Time: November 12-14, 2021 from 7:00 AM ET- 5:00 PM ET
Location: Hall E

The full posters will be posted to the presentations section of the Replimune website at https://ir.replimune.com/events-and-presentations/presentations.

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 as well as in standalone indications. 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, the potential impact of the global coronavirus pandemic and the global economy on our operations and milestones, 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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