Replimune and Incyte Enter into Clinical Trial Collaboration and Supply Agreement to Evaluate RP1 and INCB99280 in Patients with Cutaneous Squamous Cell Carcinoma

July 31, 2023

Initial study in the neoadjuvant setting designed to assess RP1 in combination with the small molecule, oral PD-L1 inhibitor, INCB99280

WOBURN, Mass. & WILMINGTON, Del.--(BUSINESS WIRE)--Jul. 31, 2023-- Replimune Group, Inc. (NASDAQ:REPL), a clinical stage biotechnology company pioneering the development of a novel portfolio of tumor-directed oncolytic immunotherapies, and Incyte (NASDAQ:INCY), a global biopharmaceutical company, today announced a clinical trial collaboration and supply agreement to study RP1, Replimune's lead product candidate, in combination with INCB99280, Incyte's small molecule oral PD-L1 inhibitor.

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"We are excited to enter into this collaboration with Incyte to explore the use of RP1 prior to surgery as we believe that our tumor-directed oncolytic immunotherapies could have a great impact in the neoadjuvant setting both in cutaneous squamous cell carcinoma (CSCC) and in other cancer types, given the high rates of complete responses we've seen to date, and data indicating RP1 is generally very well tolerated," said Robert Coffin, Chief Research and Development Officer of Replimune. "The unique potential of the RPx platform to induce a patient-specific anti-tumor immune response with an off-the-shelf treatment speaks to the practicality and broad potential utility of the approach, and exploring its use with Incyte's oral PD-L1 inhibitor has the potential to improve the patient experience further."

"We look forward to collaborating with Replimune on this study evaluating INCB99280 and RP1 in patients with CSCC. Our oral PD-L1 program has shown promising safety and efficacy in early studies thus far, and we look forward to adding to the growing body of evidence for INCB99280 and learning more about its potential to improve clinical outcomes," said Lance Leopold, M.D., Group Vice President, Clinical Development Hematology and Oncology, Incyte.

Under the terms of the agreement, Incyte will initiate and sponsor the clinical trial of INCB99280 and RP1 in patients with high risk, resectable cutaneous squamous cell carcinoma (CSCC), with the clinical trial expected to initiate in early 2024. Replimune will supply Incyte with RP1 for the study and share equally in the costs of the study.

About RP1

RP1 is Replimune's lead oncolytic immunotherapy product candidate and is based on a proprietary new strain of herpes simplex virus engineered for robust tumor selective replication 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 INCB99280

INCB99280 is a potent and selective small molecule oral PD-L1 inhibitor, which has demonstrated promising clinical activity and safety in patients with solid tumors. INCB99280 is being evaluated in multiple Phase 2 studies as monotherapy and in combination with other antitumor agents.

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 tumor-directed oncolytic immunotherapies. Replimune's proprietary RPx platform is based on a potent HSV-1 backbone with payloads added to maximize immunogenic cell death and the induction of a systemic anti-tumor immune response. The RPx platform has a unique dual local and systemic mechanism of action (MOA) consisting of direct selective virus-mediated killing of the tumor resulting in the release of tumor derived antigens and altering of the tumor microenvironment (TME) to ignite a strong and durable systemic response. This MOA is expected to be synergistic with most established and experimental cancer treatment modalities, and, with an attractive safety profile the RPx platform has the versatility to be developed alone or combined with a variety of other treatment options. For more information, please visit www.replimune.com.

About Incyte

Incyte is a Wilmington, Delaware-based, global biopharmaceutical company focused on finding solutions for serious unmet medical needs through the discovery, development and commercialization of proprietary therapeutics. For additional information on Incyte, please visit Incyte.com and follow @Incyte.

Replimune 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 design and advancement of our clinical trials, those of our collaboration partners or the combined clinical trials with our collaboration partners, the timing and sufficiency of our clinical trial outcomes to support potential approval of any of our RPx product candidates or those of, or combined with, our collaboration partners, our goals to develop and commercialize our RPx product candidates alone or with our collaboration partners, patient enrollments in our planned clinical trials, alone or with our collaboration partners, 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 RPx product candidates, alone or with our collaboration partners, changes in laws and regulations to which we are subject, political and global macro factors, 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 and the actual results of our collaboration partners and/or the combined results with our collaboration partners 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.

Incyte Forward-looking Statements

Except for the historical information set forth herein, the matters set forth in this press release, including statements regarding the potential of INCB99280 and/or RP1 to treat patients with cutaneous squamous carcinoma or for any other indication, contain predictions, estimates and other forward-looking statements.

These forward-looking statements are based on Incyte's current expectations and are subject to risks and uncertainties that may cause actual results to differ materially, including unanticipated developments in and risks related to: unanticipated delays; further research and development and the results of clinical trials possibly being unsuccessful or insufficient to meet applicable regulatory standards or warrant continued development; the ability to enroll sufficient numbers of subjects in clinical trials; determinations made by regulatory authorities; Incyte's dependence on its relationships with its collaboration partners; the efficacy or safety of Incyte's products and the products of Incyte's collaboration partners; the acceptance of Incyte's products and the products of Incyte's collaboration partners in the marketplace; market competition; sales, marketing, manufacturing and distribution requirements; and other risks detailed from time to time in Incyte's reports filed with the Securities and Exchange Commission, including its annual report and its quarterly report on Form 10-Q for the quarter ended March 31, 2023. Incyte disclaims any intent or obligation to update these forward-looking statements.

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