



Rubius Therapeutics Presents Preclinical Data for RTX-224, a Broad Immune Costimulatory Agonist, at the Society for Immunotherapy of Cancer's Annual Meeting

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U.S. FDA Recently Cleared Investigational New Drug Application for RTX-224

CAMBRIDGE Mass., Nov. 12, 2021 (GLOBE NEWSWIRE) -- Rubius Therapeutics, Inc. (Nasdaq: RUBY), a clinical-stage biopharmaceutical company that is genetically engineering red blood cells to create an entirely new class of cellular medicines called Red Cell Therapeutics™ for the treatment of cancer and autoimmune diseases, today announced the poster presentation of preclinical data for RTX-224, a broad immune costimulatory agonist for the treatment of cancer, at the Society for Immunotherapy of Cancer's (SITC) 36th Annual Meeting which is being held from November 10-14, 2021, in Washington, D.C., and virtually.

"The preclinical data presented at SITC indicate that RTX-224 stimulates both adaptive and innate immune responses, leading to an antitumor effect in our surrogate models," said Laurence Turka, M.D., chief scientific officer and head of research & translational medicine of Rubius Therapeutics. "Our preclinical model of RTX-224 demonstrated significant activation of CD4+ T cells, CD8+ T cells, antigen-presenting cells and NK cells as well as potent anti-tumor activity in a melanoma model, giving us confidence that RTX-224 may be an effective treatment for advanced solid tumors. The U.S. FDA recently cleared our Investigational New Drug application for RTX-224, and we expect to begin dosing patients during the first quarter of 2022."

Poster Title: [RTX-224, An Engineered Allogeneic Red Cell Therapeutic Expressing 4-1BBL and IL-12, Activates Immune Cells in Blood and Spleen to Promote Tumor Growth Inhibition in Mice](#)

RTX-224 is an allogeneic cellular therapy product candidate that is engineered to express hundreds of thousands of copies of 4-1BB ligand (4-1BBL) and interleukin-12 (IL-12) on the cell surface. RTX-224 is designed as a broad immune agonist of both adaptive and innate responses, activating CD8+ and CD4+ T cells, promoting antigen presentation and activating and expanding NK cells. It is expected to produce a broad and potent anti-tumor T cell response, an innate immune response and have anti-tumor activity in those tumor types with known sensitivity to T cell killing, including tumor types with high mutational burden, PD-L1 expression and prior responsiveness to checkpoint inhibitors.

Data Summary

- The mouse surrogate of RTX-224, mRBC-224, demonstrated potent anti-tumor activity in B16F10 melanoma models, intravenously and subcutaneously, that was associated with pharmacodynamic changes in the tumors, including activated CD8+ T cells, NK cells and macrophages.
- mRBC-224 distributed mainly in the spleen of tumor-bearing mice 24 hours after one dose.
- mRBC-224 treatment in mice promoted activation of NK cells, CD8+ T cells and monocytes/macrophages in the blood and spleen of naïve and tumor-bearing mice.
- RTX-224 (in vitro) and mRBC-224 (in vivo) stimulate adaptive (CD8+ T cells and CD4+ T cells) and innate (NK cells and macrophages) immune responses.
 - The combined enhancement of both adaptive and innate immune responses leads to a productive antitumor response as demonstrated in preclinical studies.

About Rubius Therapeutics

Rubius Therapeutics is a clinical-stage biopharmaceutical company developing a new class of medicines called Red Cell Therapeutics™. The Company's proprietary RED PLATFORM® was designed to genetically engineer and culture Red Cell Therapeutics™ that are selective, potent and off-the-shelf allogeneic cellular therapies for the potential treatment of several diseases across multiple therapeutic areas. Rubius' initial focus is to advance RCT™ product candidates for the treatment of cancer and autoimmune diseases by leveraging two distinct therapeutic modalities — potent cell-cell interaction and tolerance induction. Rubius Therapeutics was named among the 2020 Top Places to Work in Massachusetts by the Boston Globe, and its manufacturing site was recently named 2021 Best Places to Work in Rhode Island by Providence Business News. For more information, visit www.rubiustx.com, follow us on [Twitter](#) or [LinkedIn](#) or like us on [Facebook](#).

Forward Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, including, without limitation, statements regarding our expectations with respect to the therapeutic potential of our pipeline of Red Cell Therapeutics™, including RTX-224, plans for the SITC presentation, analyses of our preclinical data, including the impact of RTX-224 on certain immune cells and anti-tumor effects, beliefs that RTX-224 could be an effective treatment for advanced solid tumors, expectations regarding dosing, expectations for the potential for IL-12 and 4-1BB ligand to broadly induce an immune response in patients and act as a bridge between the innate and adaptive immune systems and the belief that the combined enhancement of both adaptive and innate immune responses leads to a productive antitumor response. The words "may," "will," "could," "would," "should," "expect," "plan," "anticipate," "intend," "believe," "estimate," "predict," "project," "potential," "continue," "target" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Any forward-looking statements in this press release are based on management's current expectations and beliefs and are subject

to a number of risks, uncertainties and important factors that may cause actual events or results to differ materially from those expressed or implied by any forward-looking statements contained in this press release, including, without limitation, those risks and uncertainties related to the development of our Red Cell Therapeutic product candidates, including RTX-224, and their therapeutic potential and other risks identified in our filings with the U.S. Securities and Exchange Commission (SEC), including our Quarterly Report on Form 10-Q for the quarter ended September 30, 2021, and subsequent filings with the SEC. We caution you not to place undue reliance on any forward-looking statements, which speak only as of the date they are made. We disclaim any obligation to publicly update or revise any such statements to reflect any change in expectations or in events, conditions or circumstances on which any such statements may be based, or that may affect the likelihood that actual results will differ from those set forth in the forward-looking statements. Any forward-looking statements contained in this press release represent our views only as of the date hereof and should not be relied upon as representing our views as of any subsequent date. We explicitly disclaim any obligation to update any forward-looking statements.

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