Rubius Therapeutics Announces Publication of RTX-240 Preclinical Data in Cancer Immunology, Immunotherapy

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Preclinical Data Show RTX-240 Promotes T Cell and NK Cell Activity Demonstrating Efficacy and Improved Safety Compared with a 4-1BB Agonist Antibody

CAMBRIDGE, Mass., July 15, 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™, today announced the publication of preclinical data in the peer-reviewed journal *Cancer Immunology, Immunotherapy*, for its lead clinical oncology program, RTX-240, for the treatment of adults with advanced solid tumors and relapsed/refractory acute myeloid leukemia.

The paper entitled “Anti-Tumor Effects of RTX-240: an Engineered Red Blood Cell Expressing 4-1BB Ligand and Interleukin-15” highlights preclinical findings, which demonstrate that RTX-240 activates and expands CD8+ T cells and NK cells in vitro and in vivo generating potent anti-tumor activity in both a colorectal and melanoma model. The paper is available here: https://doi.org/10.1007/s00262-021-03001-7.

“These preclinical data demonstrate RTX-240’s mechanism of action, which we’ve also seen translated to the clinic thus far. Namely, in these preclinical models, RTX-240 activated and expanded both NK and T cells capable of trafficking to the tumor and killing tumor cells, while showing only minimal toxicity due to the biodistribution of RTX-240 to the vasculature and spleen,” said Laurence Turka, M.D., chief scientific officer of Rubius Therapeutics. “Compared to a 4-1BB agonist antibody, RTX-240 was better tolerated and demonstrated a wider therapeutic window in preclinical studies, suggesting that RTX-240 could provide a more efficacious and safer option for the treatment of patients with advanced solid tumors and acute myeloid leukemia.”

“These preclinical data supported advancing RTX-240 into the clinic, where the initial clinical results have shown that RTX-240 has the ability to activate and expand a patient’s own immune system to fight cancer, leading to clinical responses in certain patients with advanced solid tumors,” said Christina Coughlin, M.D., Ph.D., chief medical officer of Rubius Therapeutics. “We are continuing to enroll patients in our ongoing Phase 1/2 clinical trial of RTX-240 in three Phase 1 arms: a monotherapy dose escalation arm in adults with relapsed/refractory or locally advanced solid tumors, a monotherapy dose escalation arm in adults with relapsed/refractory acute myeloid leukemia, and a combination therapy dose escalation arm with pembrolizumab in adults with relapsed/refractory or locally advanced solid tumors.”

About RTX-240
RTX-240, Rubius Therapeutics' lead oncology program, is an allogeneic, off-the-shelf cellular therapy product candidate that is engineered to simultaneously present hundreds of thousands of copies of the costimulatory molecule 4-1BB ligand (4-1BBL) and IL-15TP (trans-presentation of IL-15 on IL-15Rα) in their native forms. RTX-240 is designed to broadly stimulate the immune system by activating and expanding both NK and memory T cells to generate a potent anti-tumor response.

About the RTX-240 Phase 1/2 Clinical Trial
This is a Phase 1/2 open label, multicenter, multidose, first-in-human dose-escalation and expansion study designed to determine the safety and tolerability, pharmacokinetics, maximum tolerated dose, a recommended Phase 2 dose and dosing regimen of RTX-240. The trial will also assess the pharmacodynamics of RTX-240 measured by changes in T and NK cell number and function relative to baseline and anti-tumor activity. The trial has three separate Phase 1 arms: an ongoing monotherapy dose escalation arm in adults with relapsed/refractory or locally advanced solid tumors, an ongoing monotherapy dose escalation arm in adults with relapsed/refractory acute myeloid leukemia, and a combination therapy dose escalation arm with pembrolizumab in adults with relapsed/refractory or locally advanced solid tumors. The monotherapy arm of the trial in advanced solid tumors includes a Phase 2 expansion in specified tumor types.

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-240, our expectations regarding the timing, enrollment, data from and success of the future cohorts and phases of the clinical trial of RTX-240, including the Phase 1/2 clinical trial of RTX-240, our expectations regarding the biological effects of RTX-240 on innate and adaptive immunity and the related therapeutic benefits, including the therapeutic window, and beliefs about the safety and efficacy profile of RTX-240 and its potential role in the treatment of cancer, and our expectations regarding our strategy, business plans and focus. 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-240, 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 March 31, 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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