Rubius Therapeutics Announces Dosing of First Patient in Phase 1/2 Trial of RTX-224, a Broad Immune Agonist, for the Treatment of Certain Solid Tumors

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CAMBRIDGE, Mass., Jan. 13, 2022 (GLOBE NEWSWIRE) -- Rubius Therapeutics, Inc. (Nasdaq: RUBY), a clinical-stage biopharmaceutical company that is biologically engineering red blood cells to create an entirely new class of cellular medicines called Red Cell Therapeutics™ for the treatment of cancer and autoimmune disease, today announced that the first patient has been dosed in its Phase 1/2 clinical trial of RTX-224 for the treatment of patients with certain relapsed/refractory or locally advanced solid tumors, including non-small cell lung cancer, cutaneous melanoma, head and neck squamous cell carcinoma, urothelial (bladder) carcinoma and triple-negative breast cancer.

“While our lead oncology product candidate, RTX-240, is designed to broadly stimulate the immune system by activating and expanding NK and CD8+ memory T cells, we expect RTX-224 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 known responsiveness to checkpoint inhibitors,” said Larry Turka, M.D., chief scientific officer and head of research and translational medicine of Rubius Therapeutics. “Given the mechanism of action of RTX-224 and totality of our preclinical data generated to date, we believe RTX-224 will be an effective treatment for select advanced solid tumors.”

RTX-224 is an allogeneic, off-the-shelf 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.

About the RTX-224 Phase 1/2 Clinical Trial
This is a Phase 1/2 open label, multicenter, multidose, first-in-human dose-escalation and expansion study to determine the safety and tolerability, pharmacokinetics, maximum tolerated dose and a recommended Phase 2 dose and dosing regimen of RTX-224 in adult patients with certain relapsed/refractory or locally advanced solid tumors including non-small cell lung cancer, cutaneous melanoma, head and neck squamous cell carcinoma, urothelial (bladder) carcinoma and triple-negative breast cancer. The trial will also assess pharmacodynamic changes in immune cell populations relative to baseline and anti-tumor activity. The study will include a monotherapy dose escalation phase followed by an expansion phase in specified tumor types during the Phase 2 portion of the trial.

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 biologically 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 recently named among the 2021 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, analyses of expectations based on 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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