Rubius Therapeutics Announces Dosing of First Patient in Phase 1/2 Trial of RTX-240, an Allogeneic Cellular Therapy, for the Treatment of Solid Tumors

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CAMBRIDGE, Mass., May 07, 2020 (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, today announced that the first patient has been dosed in its Phase 1/2 clinical trial of RTX-240 for the treatment of patients with relapsed/refractory or locally advanced solid tumors. RTX-240 is an allogeneic, off-the-shelf Red Cell Therapeutic™ that is engineered to mimic the human immune system by stimulating adaptive and innate immunity to generate an anti-tumor immune response.

"We are excited to advance our first-ever oncology Red Cell Therapeutic, RTX-240, into clinical development and to increase our understanding of its potential to help cancer patients," said Christina Coughlin, M.D., Ph.D., chief medical officer of Rubius Therapeutics. "We are leveraging virtual capabilities to initiate clinical trial sites and concentrating on oncology-focused centers to enroll patients, while ensuring that patient and clinician safety is our top priority. By working with these oncology-focused sites, we believe we will have the greatest opportunity to enroll the trial in order to serve as many patients as possible."

RTX-240 is engineered to express a co-stimulatory molecule, 4-1BB ligand, and a cytokine, IL-15TP, on the cell's surface and is designed to broadly stimulate the immune system by activating and expanding both natural killer (NK) cells and T cells to generate a potent anti-tumor response.

"There have been many important advancements in immunotherapy treatments for cancer in recent years, but many patients do not benefit and new approaches to stimulate effective anti-tumor responses are needed in the clinic," said Melissa Johnson, M.D., associate director, Lung Cancer Research Program at Sarah Cannon Research Institute and the first investigator in the RTX-240 trial. "RTX-240 is a unique, allogeneic cellular therapy candidate that is designed to mimic how the immune system naturally functions in order to fight cancer and potentially extend the benefits of immunotherapy to a larger number of patients and in more types of cancers. We are excited to work with Rubius and evaluate RTX-240 in this clinical trial."

About the RTX-240 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-240 in adult patients with relapsed/refractory or locally advanced solid tumors. 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 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. The extent to which the COVID-19 pandemic may impact Rubius' ability to enroll patients in the trial will depend on future developments.

About RTX-240
RTX-240 is an allogeneic cellular therapy product candidate that simultaneously presents hundreds of thousands of copies of the costimulatory 4-1BB ligand (4-1BBL) and the trans-presented cytokine interleukin-15 (IL-15TP) in their native forms to activate and expand NK and T cells.
4-1BBL is a costimulatory molecule that can drive T and NK cell proliferation and activation and interferon γ (IFNγ) production. IL-15 is a cytokine that bridges innate and adaptive immunity by promoting T and NK cell proliferation and NK cell cytotoxicity. IL-15TP is a fusion of IL-15 and IL-15 receptor alpha.

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. For more information, visit www.rubiustx.com, follow us on Twitter or LinkedIn or like us on Facebook.

Forward Looking Statement
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 the planned timing, enrollment and results for our preclinical and clinical activities, including the Phase 1 clinical trial for RTX-240, our expectations regarding the impact of COVID-19 pandemic on our operations and business, including the Phase 1 clinical trial for RTX-240, our expectations regarding the therapeutic potential of our Red Cell Therapeutics, including RTX-240 for the treatment of solid tumors, and our strategy, business plans and focus, including the benefits we expect from our recent strategic shift to focus on the development of our oncology and autoimmunity pipeline. 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 and their therapeutic potential and other risks identified in our SEC filings, including our Annual Report on Form 10-K for the year ended December 31, 2019, 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 its views as of any subsequent date. We explicitly disclaim any obligation to update any forward-looking statements.

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