Rubius Therapeutics Presents Initial Clinical Results from the Ongoing Phase 1/2 Clinical Trial of RTX-240 in Advanced Solid Tumors at the American Association of Cancer Research Virtual Annual Meeting

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CAMBRIDGE, Mass., April 09, 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 reprised initial clinical results from its ongoing Phase 1/2 study of RTX-240 in advanced solid tumors at the American Association for Cancer Research (AACR) Virtual Annual Meeting. Posters will be available online tomorrow on the AACR website and Publications page of the Rubius Therapeutics website at 8:30 a.m. EDT. The data included in the poster are based on a data cutoff date of February 28, 2021.

“The clinical data shared to date demonstrate 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 Omid Hamid, M.D., Chief of Translational Research and Immunotherapy, Director of the Phase 1 Immuno-Oncology Program of The Angeles Clinic and Research Institute, a Cedars-Sinai Affiliate, and RTX-240 investigator. “Given the promising emerging safety profile, together with initial indication of clinical activity, RTX-240 represents a potentially novel therapeutic that may benefit patients with advanced-stage solid tumors, including those who have been previously treated with checkpoint inhibition.”

“Based on these initial promising results, we are continuing to enroll patients and plan to present additional clinical results from the RTX-240 Phase 1 solid tumor clinical trial by year end,” said Christina Coughlin, M.D., Ph.D., Chief Medical Officer of Rubius Therapeutics. “Additionally, by year end, we expect to select the specific solid tumor types that we plan to pursue in the Phase 2 expansion cohorts of RTX-240. We also intend to initiate a new Phase 1 arm to evaluate RTX-240 in combination with anti-PD-1 therapy in advanced solid tumors during the second half of 2021.”

Poster Title: A Phase 1 Trial of RTX-240, an Allogeneic Engineered Red Blood Cell with Cell-Surface Expression of 4-1BBL and Trans-Presented IL-15, in Patients with Advanced Solid Tumors
Session Category: Clinical Trials (Poster Session)
Session Title: Phase I Clinical Trials
Abstract Number: CT141

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 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 and a recommended Phase 2 dose and dosing regimen of RTX-240 in adult patients with relapsed/refractory or locally advanced solid tumors or with relapsed/refractory acute myeloid leukemia. 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 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 recently named among the Top Places to Work in Massachusetts by the Boston Globe, and its manufacturing site was recently named 2020 Top 5 Best Places to Work in Rhode Island among medium-sized companies 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 plans to initiate a RTX-240 Phase 2 expansion cohort, an RTX-240 Phase 1 clinical trial

in combination with an anti-PD-1 therapy in advanced solid tumors, our expectations regarding the biological effects of RTX-240 on innate and adaptive immunity and the related therapeutic benefits, our expectations regarding the initial preliminary data from RTX-240 and the related therapeutic benefits and validation of our RED PLATFORM 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 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, 2020, and subsequent filings with the SEC and risks and uncertainties related to the severity and duration of the impact of COVID-19 on our clinical trials, business and operations. 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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