Rubius Therapeutics to Present 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., March 10, 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 that the Company will present clinical results from its ongoing Phase 1/2 study of RTX-240 in advanced solid tumors during Week One of the American Association for Cancer Research (AACR) Virtual Annual Meeting being held from April 10-15, 2021. Posters will be available online on the first day of the conference on April 10 and will remain available for viewing through June 21, 2021.

“Immune agonists hold potential promise in the treatment of cancer, however, the clinical development of these agents has been limited by both severe toxicity and limited single-agent activity, leading to a narrow therapeutic window,” said Christina Coughlin, M.D., Ph.D., chief medical officer of Rubius Therapeutics. “With the development of RTX-240 in advanced solid tumors, we aim to activate two important agonist pathways with their natural ligands for enhanced potency, while potentially reducing toxicity given the biodistribution of RTX-240 to the vasculature and spleen. Ultimately, our goal with RTX-240 is to activate and expand both NK and T cells with a favorable safety profile, thus potentially widening the therapeutic window of immune agonists to allow safe and effective treatment of patients with both solid tumors and hematologic malignancies.”

Abstract 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

In January of 2021, the Company shared key takeaways from the first five cohorts (n=14) of the RTX-240 Phase 1/2 clinical trial for the treatment of advanced solid tumors. Key takeaways from the initial data included (as of January 2021):

- No treatment-related Grade 3 or Grade 4 adverse events and no dose limiting toxicities observed (n=14)
- All patients showed activation of NK or T cells or both cell types (n=14)
- In the majority of patients (n=8), all of the following were observed across dose levels:
    - Activation of NK cells, activation of T cells, expansion of NK cells and expansion of T cells

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 expectations regarding the biological effects of RTX-240 on innate and adaptive immunity and the related therapeutic benefits, including the therapeutic window, 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 . 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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