Rubius Therapeutics to Present Updated Results from Single-Agent Phase 1 Clinical Trial of RTX-240 at the American Association of Cancer Research Annual Meeting

March 8, 2022

Updated Results from Single-Agent Phase 1 Clinical Trial of RTX-240 in Advanced Solid Tumors to be Presented in a Poster at the American Association of Cancer Research Annual Meeting on Tuesday, April 12, 2022, from 9:00 a.m. – 12:30 p.m. ET

Management to Host Investor Webcast to Discuss RTX-240 Single-Agent Results in Advanced Solid Tumors and Acute Myeloid Leukemia (AML) Along with Expected Next Steps for Phase 2 Clinical Development on Friday, April 8, 2022, at 1:15 p.m. ET

CAMBRIDGE, Mass., March 08, 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 diseases, today announced that the Company will present updated results from its single-agent Phase 1 clinical trial of RTX-240 in advanced solid tumors in a poster presentation at the American Association for Cancer Research (AACR) Annual Meeting being held from April 8-13, 2022 at the Ernest N. Morial Convention Center in New Orleans, Louisiana. The Company also plans to host a webcast to discuss the results from the single-agent Phase 1 trial of RTX-240 in solid tumors and AML on April 8, 2022, at 1:15 p.m. ET, following the release of the AACR abstracts.

"In March 2021, we reported initial results from the RTX-240 Phase 1/2 clinical trial which established clinical proof of concept of RTX-240 in advanced solid tumors and clinical validation of the RED PLATFORM®, unlocking the potential of our entire oncology platform," said Pablo J. Cagnoni, M.D., president and chief executive officer of Rubius Therapeutics. "As part of our poster at AACR and planned company webcast, we look forward to presenting updated clinical results from the ongoing RTX-240 trial in patients with solid tumors and AML, including additional safety, efficacy and pharmacodynamic data from patients enrolled at higher dose levels and follow up from the patients who were included in the March 2021 announcement. We also intend to share our expected next steps for Phase 2 clinical development."

Abstract Title: Phase 1 Trial of RTX-240, Allogeneic Red Blood Cells Engineered to Express 4-1BBL and Trans-Presented IL-15, in Patients with Advanced Solid Tumors
Session Title: Phase I Clinical Trials 2
Session Date and Time: Tuesday, April 12, 2022, 9:00 a.m. – 12:30 p.m. ET
Location: New Orleans Convention Center, Exhibit Halls D-H, Poster Section 33
Poster Board Number: 12
Abstract Number: CT187

Investor Webcast
The Company plans to host a webcast on April 8, 2022, at 1:15 p.m. ET, following the release of the AACR abstracts. Details will be available on the Investors & Media section of the Rubius website.

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.

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 potential of our pipeline of Red Cell Therapeutics, our plans to announce results from our RTX-240 trial in patients with solid tumors and AML and to share expected next steps for the Phase 2 clinical development, and our expectations for and beliefs about the initial results from the RTX-240 trial and its validation of the RED PLATFORM and its impact on the potential of our entire oncology platform, the extent to which the COVID-19 pandemic may impact Rubius' ability to enroll patients in the trial will depend on future developments 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, our ability to execute on our plans and expectations, our analyses of clinical and preclinical data and other risks identified in our filings with the U.S. Securities and Exchange Commission (SEC), including our Annual Report on Form 10-K for the year ended December 31, 2021 and subsequent filings with the SEC, and risks and uncertainties related to the severity and duration of the impact of COVID-19 on our 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.

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Source: Rubius Therapeutics