Rubius Therapeutics Provides Update on Clinical Trial Progress for its Lead Oncology Product Candidate RTX-240 and Announces Planned Leadership Transition

June 30, 2020

CAMBRIDGE, Mass., June 30, 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 it has completed dosing of the first dose-escalation cohort with no observed adverse events to date in the Phase 1/2 clinical trial of RTX-240. RTX-240 is an allogeneic cellular therapy for the treatment of patients with relapsed/refractory or locally advanced solid tumors. Rubius also announced a planned change to its management team. Andrew Oh, Chief Financial Officer, will depart the Company following completion of a transition period, which will conclude on December 31, 2020. The Company has initiated a search for its next Chief Financial Officer.

“After the successful completion of the first monotherapy dose escalation cohort in our Phase 1/2 clinical trial of RTX-240, with no observed adverse events to date, we have initiated the portion of the trial where we expect to see the biological effects of RTX-240 on innate and adaptive immunity, including potential activation and increased numbers of NK cells and T cells,” said Pablo J. Cagnoni, M.D., president and chief executive officer of Rubius Therapeutics. “Based on our preclinical data, we believe these effects will translate into anti-tumor killing and clinical responses in patients. Our fully owned manufacturing facility in Smithfield, RI, continues to successfully manufacture clinical supply of RTX-240.”

The Phase 1/2 clinical trial of RTX-240 is evaluating the safety, tolerability, pharmacokinetics, maximum tolerated dose and recommended Phase 2 dose and dosing regimen of RTX-240 in adult patients with relapsed/refractory or locally advanced solid tumors. The trial is also assessing the pharmacodynamic effects of RTX-240 as measured by increased proliferation and effector function of the NK and T cell populations relative to baseline. In addition to these proliferation biomarkers, the study will also evaluate production of granzyme B, which is an indicator of activated NK and T cells capable of tumor killing. The trial is evaluating anti-tumor activity as measured by overall response rate, progression-free survival and overall survival. The ongoing dose escalation phase will be followed by expansion cohorts in specified tumor types during Phase 2 of the trial. The extent to which the COVID-19 pandemic may impact Rubius’ ability to enroll patients in the trial is uncertain and will depend on future developments.

With this clinical update, Rubius also announced the planned transition of Andrew Oh as Chief Financial Officer.

“Andy joined Rubius in 2017, when the company was privately held, and, since that time, he has helped us raise more than $450 million in capital, including our initial public offering, to support the development of our proprietary pipeline of Red Cell Therapeutics,” said Dr. Cagnoni. “He has built a world-class finance team and was instrumental in negotiating and securing our fully owned manufacturing facility that today is providing clinical supply for RTX-240. As we progress towards becoming an integrated clinical development organization with one product currently in the clinic and a second oncology Investigational New Drug Application planned for RTX-321 in HPV-positive cancers by year-end, now is the appropriate time for this important transition. We are thankful for Andy’s many contributions and wish him well on his next endeavor.”

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 gamma (IFNγ) production. IL-15 is a cytokine that bridges innate and adaptive immunity by promoting NK and T 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 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 the, our expectations regarding the therapeutic potential of our Red Cell Therapeutics, including RTX-240 for the treatment of patients with relapsed/refractory or locally advanced solid tumors, our expectations regarding the timing, enrollment, data from and success of the future cohorts and phases of the clinical trial of RTX-240, the timelines for us to file an IND for RTX-321, our expectations and timing in connection with our search for a new chief financial officer, and our strategy, business plans and focus, including our plans to present preclinical data at the AACR Annual Meeting. 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 Quarterly Report on Form 10-Q for the quarter ended March 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 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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