Rubius Therapeutics to Present Preclinical Data for RTX-321, a Red Cell Therapeutic™ Oncology Product Candidate for HPV-Positive Cancers at the American Association of Cancer Research Annual Meeting

May 15, 2020

CAMBRIDGE, Mass., May 15, 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 Company plans to present preclinical data supporting its lead artificial antigen-presenting cell (aAPC) program, RTX-321, for the potential treatment of human papillomavirus (HPV) 16-positive cancers, during the American Association for Cancer Research (AACR) Virtual Annual Meeting II. The meeting is being held from June 22-24, 2020, and all posters will be available online on the first day of the conference.

"The risk of cancer is strongly associated with HPV infection, with the high-risk strain, HPV 16, accounting for approximately 70% of all cervical cancers and 80% of head and neck cancers associated with HPV infection.[1,2] Despite the various therapies currently available, there remains a critical need for new and innovative treatment options for advanced HPV 16-associated cancers," said Laurence Turka, M.D., chief scientific officer of Rubius Therapeutics. "At this year's AACR Annual Meeting, we plan to present data in our surrogate preclinical model demonstrating that our aAPCs can activate and expand tumor-specific T cells in vivo and stimulate production of key anti-tumor effector molecules, leading to tumor control. We also expect to show that RTX-321 similarly activates and expands HPV 16-specific human T cells in vitro to become immune-effector cells. Together, these data suggest that RTX-321 may lead to durable responses in patients with HPV 16-positive cancers. We plan to file an Investigational New Drug application for RTX-321 by the end of 2020."

Abstract Title: In Vivo Efficacy and Pharmacodynamic Analysis of RTX-321, an Engineered Allogeneic Artificial Antigen Presenting Red Cell Therapeutic
Session Date/Time: June 22, 2020
Session Title: Late-Breaking Research: Immunology 1
Abstract Number: LB-082

About RTX-321
RTX-321 is an allogeneic, artificial antigen-presenting Red Cell Therapeutic product candidate designed to induce a tumor-specific response by selectively activating and expanding tumor-specific T cells against a target antigen. It is engineered to express an HPV 16 antigen bound to MHC I, along with 4-1BBL and IL-12, on the cell surface to mimic T cell APC interactions and thus activate and expand tumor-specific T cells present within the patient, bypassing the dependence on host APCs typically required for cancer vaccines and eliminating the need for manufacturing patient-derived T cells as with CAR T therapies.

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-321 for the treatment of HPV 16-positive tumors, the timelines for us to file an IND for RTX-321, 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. 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.

[1] Saraiya M, et. al., US Assessment of HPV Types in Cancers: Implications for Current and 9-Valent HPV Vaccines. J Natl Cancer Inst. 2015 Jun; 107(6): djv086.

[2] Ndiaye, C., et al., HPV DNA, E6/E7 mRNA, and p16INK4a detection in head and neck cancers: a systematic review and meta-analysis. Lancet Oncol 2014; 15: 1319–31.

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