



## Rubius Therapeutics Highlights Preclinical Data for RTX-321, a Red Cell Therapeutic™ Oncology Product Candidate for HPV-Positive Cancers, at the American Society of Gene & Cell Therapy 23rd Annual Meeting

May 12, 2020

CAMBRIDGE, Mass., May 12, 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 presented preclinical data supporting its lead artificial antigen-presenting cell (aAPC) program, RTX-321, for the potential treatment of HPV 16-positive tumors at the American Society of Gene and Cell Therapy 23rd Annual Meeting. The meeting is being held virtually from May 12 – 15, 2020.

"Today, we presented preclinical in vitro data supporting the development of RTX-321 for the treatment of HPV 16-positive tumors by demonstrating that we can expand the different cell populations - effector and long-lived memory CD8+ cells - that are critical for delivering and maintaining long-term, anti-tumor responses in patients," said Laurence Turka, M.D., chief scientific officer of Rubius Therapeutics. "Additionally, we presented data showing that our aAPC platform can expand both naïve and exhausted CD4+ T cells. CD4+ T cells help coordinate an immune response by stimulating other immune cells to fight cancer. By enhancing the expansion, persistence and functionality of both naïve and exhausted CD4+ T cells, we may be able to harness the full complement of tumor-specific CD4+ T cells to achieve 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."

### Data Summaries

#### [An Engineered Allogeneic Artificial Antigen Presenting Red Cell Therapeutic, RTX-321, for HPV16+ Associated Cancers Promotes Antigen-Specific T Cell Activation & Expansion \(Poster #321\)](#)

RTX-321 is an allogeneic aAPC therapy product candidate that is engineered to induce a tumor-specific immune response by expanding antigen-specific T cells. RTX-321 expresses an HPV peptide antigen bound to major histocompatibility complex (MHC) class I, 4-1BBL, a co-stimulatory signal, and IL-12, a cytokine, on the cell surface to mimic human T cell-APC interactions.

- Presentation of an HPV peptide bound to MHC I engages the T cell receptor and initiates T-cell signaling and early activation on HPV antigen-specific cells
- RTX-321 induces activation determined by upregulation of 4-1BB, CD25, and PD-1 expression
- All three signals (an HPV peptide antigen bound to MHC I, 4-1BBL and IL-12) are required for robust expansion, effector memory phenotype, and effector molecule production of HPV antigen-specific cells
- RTX-321 induces T-cell mediated responses in an antigen-specific manner in vitro

#### [Engineered Red-Cell Therapeutics \(RCT\) as Artificial Antigen Presenting Cells Promote In Vitro Expansion of Both Naïve and Exhausted CD4+ T Cells](#)

(Poster #1149)

Red Cell Therapeutic (RCT) aAPCs were engineered to express an OVA peptide bound to MHC class II, 4-1BBL and IL-12 to mimic and amplify normal antigen-presenting cell-T cell interactions to drive both the quantity and quality of antigen-specific CD4 T cell responses.

- RCT MHC II aAPC (RCT-1-Ab-OVA-CD80) with IL-7 or IL-12 expands both naïve and exhausted I-Ab-OVA-specific OT-2 mouse CD4+ T cells
- Co-incubation of OT-2 cells with RCT-I-Ab-OVA-CD80 and RCT-IL-12 drives memory formation and Th1 polarization for both naïve and exhausted OT-2 cells
- Co-incubation of OT-2 cells with RCT-I-Ab-OVA-CD80 and RCT-IL-7 results in additive effects on expansion and memory formation of exhausted OT-2 cells
- Taken together, these results demonstrate the potential for an MHC Class II-specific aAPC platform to enhance the expansion, persistence and functionality of both naïve and exhausted CD4+ T cells in vitro

### 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](http://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. 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 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.

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