



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

June 22, 2020

### RTX-321 May Induce Epitope Spreading and Long-Term Tumor Memory

CAMBRIDGE, Mass., June 22, 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 the presentation of 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.

"These preclinical data presented at AACR suggest that RTX-321 may promote epitope spreading, meaning that RTX-321 may induce the expansion of an immune response to secondary epitopes, or antigens, that are not expressed on RTX-321. This finding is important because it suggests that RTX-321 may create a broad and effective immune response against multiple tumor antigens," said Laurence Turka, M.D., chief scientific officer of Rubius Therapeutics. "Additionally, the preclinical surrogate of RTX-321 induces tumor-specific memory, potentially enabling the body to remember a cancer's identity, which is critical to providing long-term protection from recurrence of the tumor. Taken together, these findings support the potential of RTX-321 as an effective antigen-specific therapy for HPV 16-positive cancers. We plan to file the Investigational New Drug application for this program by the end of 2020."

#### Data Summary

[In Vivo Efficacy and Pharmacodynamic Analysis of RTX-321, an Engineered Allogeneic Artificial Antigen Presenting Red Cell Therapeutic](#) – Poster #LB-082

RTX-321 is an investigational allogeneic aAPC therapy 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 proteins, 4-1BBL – a co-stimulatory signal – and IL-12 – a cytokine – on the cell surface to mimic human T cell-APC interactions.

- Treatment with mRBC-321, a mouse surrogate of RTX-321, leads to tumor cures and long-term memory based on protection from re-challenge with tumor cells
- Protection of mice challenged with parental cells lacking the original antigen strongly suggests treatment with mRBC-321 promotes epitope spreading
- mRBC-321 inhibits tumor growth without adoptive transfer, which is correlated to endogenous T cell expansion in the tumor
- RTX-321 activates and expands HPV-antigen-specific TCR-transduced primary T cells *in vitro*
- Overall, mRBC-321 and RTX-321 can selectively engage and activate antigen-specific T cells, allowing for robust expansion and differentiation into effector and long-lasting anti-tumor memory cells
- Taken together, these findings support the potential of RTX-321 as an effective treatment for HPV 16-positive cancers

#### 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 our expectations regarding the therapeutic potential of RTX-321 for the treatment of HPV 16-positive tumors, our expectations regarding IND-enabling studies for RTX-321, the timeline 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 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.

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