



## Rubius Therapeutics Announces Publication of RTX-321 Preclinical Data in Nature Communications

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### Preclinical Data Demonstrate RTX-321 Potently Activates and Expands HPV 16-Reactive Anti-Tumor T Cells and Provides Broad Immune Stimulation

CAMBRIDGE, Mass., May 12, 2021 (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 called Red Cell Therapeutics™, today announced the publication of preclinical data in the peer-reviewed journal *Nature Communications*, for its lead artificial antigen-presenting (aAPC) cell program, RTX-321, for the potential treatment of human papillomavirus (HPV) 16-positive cancers. RTX-321 is an allogeneic, off-the-shelf Red Cell Therapeutic product candidate that is engineered as an aAPC with a dual mechanism of action: to boost HPV 16-specific CD8+ T cell responses and promote broad stimulation of both innate and adaptive immune responses. Rubius Therapeutics is currently enrolling patients with persistent, recurrent, or metastatic, unresectable, HPV 16-positive cancers, including cervical cancer, head and neck squamous cell carcinoma (HNSCC) and anal cancer, in a Phase 1 clinical trial.

The paper entitled “Engineered red blood cells as an off-the-shelf allogeneic anti-tumor therapeutic” highlights preclinical findings demonstrating that the surrogate model of RTX-321 induced a target antigen-specific immune response, epitope spreading, memory formation as well as broad immune stimulation. This suggests that in patients, an effective immune response could be generated against multiple HPV antigens, and potentially enable the patient’s own immune system to remember a cancer’s identity, which could lead to long-term protection from tumor recurrence. The paper is available here: <https://rdcu.be/ckodl>.

“These preclinical findings support the potential of RTX-321 as an effective antigen-specific therapy for advanced HPV 16-positive cancers, where few treatment options exist in the metastatic setting for this group of patients. Our publication describes an elegant mechanism of action for RTX-321, combining antigen-specific responses with the addition of broad immune stimulation,” said Laurence Turka, M.D., chief scientific officer of Rubius Therapeutics. “We are very excited about the potential of this investigational therapy and plan to share initial clinical results from our Phase 1 clinical trial in the first quarter of 2022.”

For additional background on the paper, see accompanying article on Rubius Therapeutics’ RED PLATFORM® from the authors in Nature’s Behind the Paper Channel, [here](#).

#### About HPV 16-Positive Cancers

Human papillomavirus (HPV) 16 is associated with approximately 70 percent of cervical cancers, approximately 40 percent of head and neck squamous cell carcinoma (HNSCC) arising in the oropharynx, approximately 25-40 percent of HNSCC arising in other locations and approximately 80-85 percent of anal cancers. A critical need remains for better treatment options for advanced HPV 16-associated cancers. The prognosis remains poor for patients with metastatic disease with few treatment options beyond the first-line setting.

#### About the RTX-321 Clinical Trial

Rubius Therapeutics is enrolling patients in a Phase 1 open-label, multicenter, monotherapy dose escalation, first-in-human study of RTX-321 for the treatment of patients that are HLA-A\*02:01-positive with persistent, recurrent, or metastatic, unresectable, HPV 16-positive cancers, including unresectable cervical cancer (squamous, adeno, or adenosquamous histology), head and neck squamous cell carcinoma (including of the nasal and oral cavities, larynx, hypopharynx, nasopharynx, and oropharynx) and squamous cell cancer of the anal canal that is not amenable to curative therapy. The purpose of the trial is to determine the safety and tolerability, recommended Phase 2 dose and pharmacology, and antitumor activity of RTX-321. For more information about the Phase 1 clinical trial of RTX-321, please visit [clinicaltrials.gov](https://clinicaltrials.gov) (NCT04672980).

#### About RTX-321

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

#### 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. Rubius Therapeutics was named among the 2020 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](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 our pipeline of Red Cell Therapeutics, including the dual mechanism of RTX-321 for the treatment of HPV 16-positive cancers, the potential therapeutic benefits of RTX-321, timelines

related to the Phase 1 clinical trial of RTX-321, 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 and other risks identified in our SEC filings, including our Quarterly Report on Form 10-Q for the quarter ended March 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. We explicitly disclaim any obligation to update any forward-looking statements.

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