



Rubius Therapeutics Announces Issuance of Multiple U.S. Patents for its Red Cell Therapeutic Programs

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First U.S. Composition of Matter Patent Issued for Genetically Engineered Red Cell

CAMBRIDGE, Mass., June 05, 2019 (GLOBE NEWSWIRE) -- Rubius Therapeutics, Inc. (Nasdaq: RUBY), a clinical-stage biopharmaceutical company that is generating red blood cells and bioengineering them into an entirely new class of allogeneic, off-the-shelf cellular medicines, today announced the issuance of three patents from the U.S. Patent and Trademark Office (USPTO) related to its rare disease and oncology programs and platforms. Two of the issued patents cover composition of matter and methods of use for the Company's lead investigational cellular therapy, RTX-134, for the treatment of patients with phenylketonuria (PKU). The third patent, the Company's first issued composition of matter patent in immuno-oncology, relates to human cells having a checkpoint inhibitor linked to the cell surface. In total, Rubius Therapeutics has 29 patent families and more than 125 pending patent applications worldwide.

"The issuance of these key patents strengthens our growing intellectual property portfolio and demonstrates our leadership position in the field of cellular therapy," said Pablo J. Cagnoni, M.D., chief executive officer of Rubius Therapeutics. "The RTX-134 composition of matter and methods of use patents, along with our immuno-oncology patent, highlight the breadth of both our platform and our patent estate. We intend to continue to pursue worldwide patent protection for our novel compositions, methods, treatment, dosing, formulations and methods of manufacturing related to our Red Cell Therapeutics."

RTX-134 Patent Issuances

Rubius Therapeutics' lead RCT™ product candidate is RTX-134, an allogeneic, off-the-shelf cellular therapy for the potential treatment of patients with PKU. U.S. Patent No. 10,301,594, the Company's first composition of matter patent for a RCT, covers genetically-engineered erythroid cells, such as RTX-134, that have the enzyme phenylalanine ammonia lyase (PAL) inside the cell. The new use patent, U.S. Patent No. 10,253,296, covers methods of decreasing phenylalanine using genetically-engineered erythroid cells, such as RTX-134, that have PAL inside the cell. RTX-134 is designed to circulate in the blood stream and degrade toxic levels of phenylalanine that accumulate due to a deficiency in the phenylalanine hydroxylase (PAH) enzyme. Compared to current therapeutic interventions, RTX-134 may have a more sustained treatment effect given the 120-day circulating time of red blood cells and may have a lower incidence of immune-driven adverse events, including the formation of neutralizing antibodies to the therapeutic enzyme, which often results in a reduction in efficacy. As a result, RTX-134 may provide a more efficacious, safe and convenient treatment option for patients. The Company expects to begin enrollment in a Phase 1b clinical study this quarter with initial clinical data anticipated during the second half of 2019.

Immuno-Oncology Patent Issuance

The Company's first issued immuno-oncology patent, U.S. Patent No. 10,260,038, is a composition of matter patent directed to any human cell onto which any checkpoint inhibitor may be linked via an endogenous sortase recognition sequence. This patent is exclusively licensed from the Whitehead Institute for Biomedical Research at the Massachusetts Institute of Technology. Rubius Therapeutics' oncology and immune-oncology estate includes more than 25 patents and patent applications worldwide.

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 rare diseases, cancer and autoimmune diseases by leveraging three distinct therapeutic modalities — cellular shielding, potent cell-cell interaction and tolerance induction. For more information, visit www.rubiustx.com, or follow us on [Twitter](#) and [LinkedIn](#).

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 planned timing and results for our preclinical and clinical activities, including the Phase 1b clinical trial for RTX-134 for the treatment of PKU, our ability to further develop our RCT product candidates, our expectations regarding the therapeutic potential of our RCTs, including RTX-134 for the treatment of PKU, our expectations regarding the potential benefits of our newly issued patents, including regarding exclusivity for RTX-134 and our leadership position in patenting Red Cell Therapeutics, our expectations regarding the potential of our immuno-oncology patent estate, the timing and success of our future patent applications, 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 RCT 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, 2019, 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.

Contacts:

Lori Melançon
Vice President, Corporate Communications and Investor Relations
+1 (617) 949-5296
lori.melancon@rubiustx.com

Media Contact:

Dan Budwick
1AB
+1 (973) 271-6085
dan@1abmedia.com



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