Precision BioSciences Announces FDA Accepts IND for PBCAR19B, a Next-Generation, Stealth Cell, CD19 Allogeneic CAR T Candidate for Non-Hodgkin Lymphoma

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Phase 1 clinical trial of PBCAR19B for patients with relapsed/refractory NHL expected to begin by mid-2021

DURHAM, N.C., Jan. 19, 2021 (GLOBE NEWSWIRE) -- Precision BioSciences, Inc. (Nasdaq: DTIL), a clinical stage biotechnology company dedicated to improving life with its wholly proprietary ARCUS® genome editing platform, today announced that the U.S. Food and Drug Administration (FDA) has accepted the Investigational New Drug (IND) application for PBCAR19B, a next-generation, stealth cell, CD19 product candidate for patients with relapsed/refractory (R/R) Non-Hodgkin Lymphoma (NHL).

"We are pleased to receive IND clearance for PBCAR19B, which has shown in preclinical studies, to delay both T cell and natural killer cell-mediated allogeneic rejection," said Matt Kane, Chief Executive Officer of Precision BioSciences. "We believe that the ability to reduce rejection by both cell types holds potential for improved persistence of allogeneic CAR T cells and that, by bringing PBCAR19B into the clinic while continuing to develop our lead allogenic candidate PBCAR0191, we have two opportunities to achieve our goal of producing deep and durable clinical responses."

The Phase 1 study will be a non-randomized, open-label, single-dose, dose-escalation and dose-expansion study deigned to evaluate the safety and clinical activity of PBCAR19B at increasing flat dose levels (2.7×10^8 - 8.1×10^8 CAR T cells) in patients with R/R NHL. The primary objective of the study is to identify the maximum tolerated dose and any dose-limiting toxicities.

About PBCAR19B
PBCAR19B is a next-generation, stealth cell candidate for patients with CD19-positive malignancies such as relapsed/refractory Non-Hodgkin Lymphoma. PBCAR19B is designed to improve the persistence of allogeneic CAR T cells following infusion by preventing rejection by T cells and natural killer (NK) cells. In addition to the CAR gene, the stealth vector carries a short hairpin RNA (shRNA) that suppresses expression of beta-2 microglobulin (B2M), a component of Class 1 major histocompatibility complex (MHC) molecules found on the cell surface. Reducing or knocking down Class 1 expression on allogeneic CAR T cells has been shown to reduce CAR T cell killing by cytotoxic T cells. The stealth vector also carries a HLA-E gene intended to prevent rejection of CAR T cells by NK cells that can be stimulated as a result of reduced MHC molecule expression on the cell surface.

About Precision BioSciences, Inc.
Precision BioSciences, Inc. is a clinical stage biotechnology company dedicated to improving life (DTIL) with its wholly proprietary ARCUS® genome editing platform. ARCUS is a highly specific and versatile genome editing platform that was designed with therapeutic safety, delivery, and control in mind. Using ARCUS, the Company's pipeline consists of multiple "off-the-shelf" CAR T immunotherapy clinical candidates and several *in vivo* gene correction therapy candidates to cure genetic and infectious diseases where no adequate treatments exist. For more information about Precision BioSciences, please visit www.precisionbiosciences.com.

About Precision's Collaboration with Servier
Under the terms of the agreement with Servier, Precision is solely responsible for early-stage research activities as well as PBCAR0191 and PBCAR19B Phase 1/2a clinical trial execution and clinical supply. Servier has the exclusive right to opt in for late-stage development and commercialization, and Precision has the right to participate in the development and commercialization of any licensed products resulting from the collaboration through a 50/50 co-development and co-promotion option in the United States.

Forward Looking Statements
This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements contained in this press release that do not relate to matters of historical fact should be considered forward-looking statements, including, without limitation, statements regarding the expected commencement of a Phase 1 clinical trial for PBCAR19B and expected results from clinical trials involving PBCAR19B and PBCAR0191. In some cases, you can identify forward-looking statements by terms such as "aim," "anticipate," "believe," "could," "expect," "should," "plan," "intend," "estimate," "target," "mission," "goal," "may," "will," "would," "should," "could," "target," "potential," "project," "predict," "contemplate," "potential," or the negative thereof and similar words and expressions.

Forward-looking statements are based on management's current expectations, beliefs and assumptions and on information currently available to us. Such statements are subject to a number of known and unknown risks, uncertainties and assumptions, and actual results may differ materially from those expressed or implied in the forward-looking statements due to various important factors, including, but not limited to: our ability to become profitable; our ability to procure sufficient funding and requirements under our current debt instruments and effects of restrictions thereunder; risks associated with raising additional capital; our operating expenses and our ability to predict what those expenses will be; our limited operating history; the success of our programs and product candidates in which we expend our resources; our limited ability or inability to assess the safety and efficacy of our product candidates; our dependence on our ARCUS technology; the initiation, cost, timing, progress, achievement of milestones and results of research and development activities, preclinical or greenhouse studies and clinical or field trials; public perception about genome editing technology and its applications; competition in the genome editing, biopharmaceutical, biotechnology and agricultural biotechnology fields; our or our collaborators' ability to identify, develop and commercialize product candidates; pending and potential liability lawsuits and penalties against us or our collaborators related to our technology and our product candidates; the U.S. and foreign regulatory landscape applicable to our and our collaborators'

development of product candidates; our or our collaborators' ability to obtain and maintain regulatory approval of our product candidates, and any related restrictions, limitations and/or warnings in the label of an approved product candidate; our or our collaborators' ability to advance product candidates into, and successfully design, implement and complete, clinical or field trials; potential manufacturing problems associated with the development or commercialization of any of our product candidates; our ability to obtain an adequate supply of T cells from qualified donors; our ability to achieve our anticipated operating efficiencies at our manufacturing facility; delays or difficulties in our and our collaborators' ability to enroll patients; changes in interim "top-line" and initial data that we announce or publish; if our product candidates do not work as intended or cause undesirable side effects; risks associated with applicable healthcare, data protection, privacy and security regulations and our compliance therewith; the rate and degree of market acceptance of any of our product candidates; the success of our existing collaboration agreements, and our ability to enter into new collaboration arrangements; our current and future relationships with and reliance on third parties including suppliers and manufacturers; our ability to obtain and maintain intellectual property protection for our technology and any of our product candidates; potential litigation relating to infringement or misappropriation of intellectual property rights; our ability to effectively manage the growth of our operations; our ability to attract, retain, and motivate key executives and personnel; market and economic conditions; effects of system failures and security breaches; effects of natural and manmade disasters, public health emergencies and other natural catastrophic events effects of the outbreak of COVID-19, or any pandemic, epidemic or outbreak of an infectious disease; insurance expenses and exposure to uninsured liabilities; effects of tax rules; risks related to ownership of our common stock and other important factors discussed under the caption "Risk Factors" in our Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2020, as any such factors may be updated from time to time in our other filings with the SEC, which are accessible on the SEC's website at www.sec.gov and the Investors & Media page of our website at investor.precisionbiosciences.com.

All forward-looking statements speak only as of the date of this press release and, except as required by applicable law, we have no obligation to update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise.

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