Precision BioSciences Doses First Patient in Phase 1 Allogeneic CAR T Clinical Trial of PBCAR19B Immune Evading Stealth Cell for Relapsed/Refractory Non-Hodgkin Lymphoma

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DURHAM, N.C.--(BUSINESS WIRE)--Jul. 1, 2021-- Precision BioSciences, Inc. (Nasdaq: DTIL), a clinical stage biotechnology company developing allogeneic CAR T and *in vivo* gene correction therapies with its ARCUS® genome editing platform, today announced that the first patient has been dosed in its Phase 1 clinical trial with PBCAR19B, an immune evading allogeneic CAR T stealth cell candidate for patients with relapsed/refractory (R/R) non-Hodgkin lymphoma (NHL).

"We are excited to have dosed the first patient in our Phase 1 trial of PBCAR19B, a next-generation, CD19-targeted candidate incorporating our immune evading stealth cell technology. This is our fourth CAR T program in the clinic, demonstrating the modularity of ARCUS for allogeneic CAR T therapies," said Alan List, M.D., Chief Medical Officer of Precision BioSciences. "Moreover, we believe that our ARCUS-edited stealth cell technology holds the potential to safely improve the persistence of allogeneic CAR T cells without the need for prolonged immunosuppression, which may ultimately lead to deeper and more durable responses for patients."

The Phase 1 study will be a non-randomized, open-label, single-dose, dose-escalation and dose-expansion study designed to evaluate the safety and clinical activity of PBCAR19B at flat dose levels beginning at 2.7×10^8 with the ability to dose up to 8.1×10^8 CAR T cells per patient, following standard lymphodepletion[1] in patients with R/R NHL. The first dose level of PBCAR19B is comparable to dose level 3 of the PBCAR0191 CAR T. The primary objective of the study is to identify the maximum tolerated dose and any dose-limiting toxicities. Clinical trial material for this study is generated at the Company's in-house Manufacturing Center for Advanced Therapeutics (MCAT) in Durham, North Carolina.

About PBCAR19B (Clinical Trials Study Identifier: NCT04649112)
PBCAR19B is a next-generation, immune evading stealth cell candidate for patients with CD19-positive malignancies such as R/R NHL. PBCAR19B is designed to improve the expansion and persistence of allogeneic CAR T cells following infusion by reducing rejection by T cells and NK cells. In addition to the CAR gene, the PBCAR19B stealth cell vector carries a short hairpin RNA that suppresses expression of beta-2 microglobulin, a component of Class I Major Histocompatibility Complex (MHC) molecules found on the cell surface. Reducing or knocking-down Class I MHC expression on allogeneic CAR T cells has been shown to reduce CAR T cell killing by cytotoxic T cells. The PBCAR19B vector also carries an HLA-E gene intended to reduce 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's Allogeneic CAR T Platform
Precision is advancing a pipeline of cell-phenotype optimized allogeneic CAR T therapies, leveraging fully scaled, proprietary manufacturing processes. The platform is designed to maximize the number of patients who can potentially benefit from CAR T therapy. Precision carefully selects high-quality T cells derived from healthy donors as starting material, then uses its ARCUS genome editing technology to modify the cells via a single-step engineering process. By inserting the CAR gene at the T cell receptor (TCR) locus, this process knocks in the CAR while knocking out the TCR, creating a consistent product that can be reliably and rapidly manufactured and is designed to prevent graft-versus-host disease. Precision optimizes its CAR T therapy candidates for immune cell expansion in the body by maintaining a high proportion of naïve and central memory CAR T cells throughout the manufacturing process and in the final product.

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.

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 clinical development of PBCAR19B, the potential clinical benefit of our allogeneic CAR T product candidates and the further development of our ARCUS platform. 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 March 31, 2021, 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.

[1] Standard lymphodepletion = Fludarabine (30 mg/m/day for 3 days) plus cyclophosphamide (500 mg/m^2/day for 3 days)

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