Precision BioSciences Announces Dosing of First Patient in Phase 1/2a Clinical Trial of PBCAR20A for Relapsed/Refractory NHL, CLL, and SLL

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PBCAR20A targets CD20 and is the Company's second investigational allogeneic CAR T candidate advanced to the clinic

FDA has authorized Precision to begin dosing with PBCAR20A at Dose Level 2

DURHAM, N.C., April 07, 2020 (GLOBE NEWSWIRE) -- Precision BioSciences, Inc. (Nasdaq: DTIL), a life sciences company dedicated to improving life through the application of its pioneering, proprietary ARCUS® genome editing platform, today announced the initiation of patient dosing in a Phase 1/2a clinical trial of its second off-the-shelf (allogeneic) chimeric antigen receptor (CAR) T cell therapy candidate, PBCAR20A.

Wholly owned by Precision, PBCAR20A is an investigational allogeneic anti-CD20 CAR T therapy in development for the treatment of two separate cohorts of patients. The first cohort will enroll patients with relapsed/refractory (R/R) non-Hodgkin lymphoma (NHL), and the second will include patients with R/R chronic lymphocytic leukemia (CLL) or R/R small lymphocytic lymphoma (SLL). The NHL cohort will include patients with mantle cell lymphoma (MCL), an aggressive subtype of NHL, for which Precision BioSciences has received orphan drug designation from the United States Food and Drug Administration (FDA).

"As we navigate the unprecedented COVID-19 pandemic, we are incredibly grateful to patients and their families, investigators and their clinical study sites, and our employees and partners for advancing a study that has the potential to treat very challenging and life threatening cancers," commented Matt Kane, CEO and co-founder of Precision BioSciences. "It is very encouraging that, based on the safety profile we have so far observed with our first CAR T candidate, PBCAR0191, the FDA authorized us to begin dosing PBCAR20A at what was expected to be our second dose level. It is a testament to the progress we have made over the past year that Precision now has two CAR T programs in clinical trials."

"We believe that PBCAR20A provides the opportunity to apply our ARCUS technology and cell engineering platform to target CD20, a validated antigen in NHL and CLL/SLL, which often remains expressed in patients previously treated with CD19-targeted therapies. This approach may allow us to address some patients who failed CD19 CAR T treatment and/or consider earlier line treatment to achieve meaningful clinical benefit in patients suffering with these diseases," noted Chris Heery, MD, Chief Medical Officer of Precision BioSciences. "Additionally, receiving orphan drug designation from the FDA for MCL provides a special opportunity to serve a group of patients who have a poor prognosis with currently available treatments."

In preclinical disease models, PBCAR20A demonstrated potent *in vivo* clearance of $CD20^+$ tumor cells and overall tumor volume reduction, with no evidence of graft-versus-host disease. Based on the safety profile observed from early dose levels in the Company's ongoing Phase 1/2a study of PBCAR0191, the FDA authorized dosing in this Phase 1/2a study of PBCAR20A to begin at what was originally designed to be Dose Level 2 ($1x10^6$ cells/kg), with the subsequent dose level expected to be $3x10^6$ cells/kg.

About the PBCAR20A Clinical Trial
PBCAR20A is being evaluated in a Phase 1/2a multicenter, nonrandomized, open-label, dose-escalation and dose-expansion clinical trial in adult NHL and CLL/SLL patients. The trial will be conducted at multiple U.S. sites. For more information visit www.clinicaltrials.gov, study identifier number NCT04030195.

Precision's Off-The-Shelf 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 utilizes its unique 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 is dedicated to improving life (DTIL) through its proprietary genome editing platform, "ARCUS." Precision leverages ARCUS in the development of its product candidates, which are designed to treat human diseases and create healthy and sustainable food and agriculture solutions. Precision is actively developing product candidates in three innovative areas: allogeneic CAR T immunotherapy, *in vivo* gene correction, and food. For more information regarding Precision, 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 statements regarding the Company's plans for its Phase 1/2a clinical trial for PBCAR20A, the potential results with respect to PBCAR20A and the expectation for additional CAR T candidates to enter clinical trials. In some cases, you can identify forward-looking statements by terms such as "anticipate," "believe,"

“could,” “expect,” “should,” “plan,” “intend,” “estimate,” “target,” “mission,” “may,” “will,” “would,” “should,” “could,” “target,” “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; our limited operating history; the success of our programs and product candidates; our dependence on our ARCUS technology; the initiation, cost, timing, progress and results of research and development activities, preclinical or greenhouse studies and clinical or field trials; our or our collaborators’ ability to identify, develop and commercialize product candidates; our or our collaborators’ ability to advance product candidates into, and successfully complete, clinical or field trials; 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; the laws and regulatory landscape that will apply to our and our collaborators’ development of product candidates; our ability to achieve our anticipated operating efficiencies as we commence manufacturing operations at our new facility; delays or difficulties in enrolling patients in clinical trials; our ability to obtain and maintain intellectual property protection for our technology and any of our product candidates; potential litigation relating to infringement or misappropriate of intellectual property rights; if our product candidates do not work as intended or cause undesirable side effects the potential for off-target editing or other adverse events, undesirable side effects or unexpected characteristics associated with any of our product candidates; risks associated with applicable healthcare, data 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; our ability to enter into new collaboration arrangements; public perception about genome editing technology and its applications; competition in the genome editing, biopharmaceutical, biotechnology and agricultural biotechnology fields; potential manufacturing problems associated with any of our product candidates; pending and potential liability lawsuits and penalties related to our technology, our product candidates; the outbreak of the novel coronavirus disease (COVID-19); our current and future relationships with third parties; our ability to effectively manage the growth of our operations; our ability to attract, retain, and motivate key scientific and management personnel; effects of natural or manmade disasters, public health emergencies and other natural catastrophic events; insurance expenses and exposure to uninsured liabilities; market and economic conditions; dilution and fluctuations in our stock price; and other important factors discussed under the caption “Risk Factors” in our Annual Report on Form 10-K for the fiscal year ended December 31, 2019, as supplemented by the risk factor contained in our Current Report on Form 8-K filed with the SEC on April 6, 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.

All forward-looking statements speak only as of the date of this press release and, except as required by applicable law, we do not plan to publicly 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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