Precision BioSciences Announces Dosing of First Patient in Phase 1/2a Clinical Trial of PBCAR269A for Multiple Myeloma

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-PBCAR269A Targets BCMA for the Treatment of Relapsed/Refractory Multiple Myeloma and is the Company's Third Investigational Allogeneic CAR T Candidate Advanced to the Clinic –

-PBCAR269A is the First Off-the-Shelf Candidate Produced at In-House Manufacturing Center-

DURHAM, N.C., June 08, 2020 (GLOBE NEWSWIRE) -- Precision BioSciences, Inc. (Nasdaq: DTIL), a clinical stage biotechnology company dedicated to improving life with its novel and proprietary ARCUS® genome editing platform, today announced that the first patient has been dosed in a Phase 1/2a clinical trial of PBCAR269A, its third allogeneic chimeric antigen receptor (CAR) T cell therapy candidate. Wholly-owned by Precision, PBCAR269A targets the B-cell maturation antigen (BCMA) and is being evaluated for the treatment of relapsed/refractory multiple myeloma.

"PBCAR269A is our third off-the-shelf CAR T candidate to advance into the clinic; the second within the last two months. Despite the uncertain impact of COVID-19 on patients and the healthcare community at large, we maintained our focus and dedication that have enabled continued execution during the pandemic," commented Matt Kane, CEO and co-founder of Precision Biosciences. "Notably, this will be our first study for which all clinical trial material will be produced at our in-house manufacturing facility."

"There remains significant unmet need for a broadly available and well-tolerated treatment for patients with relapsed or refractory Multiple Myeloma," said Chris Heery, MD, Chief Medical Officer of Precision BioSciences. "We are committed to improving the access of CAR T therapies for more patients. We appreciate the commitment of our clinical sites to start enrollment ahead of schedule, even during these difficult times, and the willingness of patients to take part in this trial."

In preclinical disease models, PBCAR269A demonstrated potent *in vivo* clearance of BCMA+ tumor cells and overall tumor volume reduction, with no evidence of graft-versus-host disease (GVHD). Clinical trial material for this study is generated at the Company's in-house Manufacturing Center for Advanced Therapeutics (MCAT) in Durham, North Carolina. PBCAR269A has received Orphan Drug Designation from the FDA for the treatment of multiple myeloma.

About the PBCAR269A Clinical Trial
PBCAR269A is being evaluated in a Phase 1/2a multicenter, nonrandomized, open-label, parallel assignment, single-dose, dose-escalation, and dose-expansion study to evaluate the safety and clinical activity of PBCAR269A in adults with relapsed/refractory multiple myeloma. The starting dose of PBCAR269A will be 6×10^5 CAR T cells/kg body weight. Subsequent cohorts will be treated with escalating doses to a maximum dose of 6×10^6 CAR T cells/kg body weight. The trial will be conducted at multiple U.S. sites. For more information, visit www.clinicaltrials.gov, study identifier number NCT04171843.

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 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, Inc. is a clinical stage biotechnology company dedicated to improving life (DTIL) with its novel and 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. Elo Life Systems is a wholly-owned subsidiary of Precision BioSciences also using ARCUS to benefit human health and wellness with novel food products that enhance the nutrition and diversity of global food supply. 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 Company's timing of clinical trials and results therefrom involving PBCAR269A and the expected benefits of producing clinical trial material at the Company's in-house manufacturing facility. 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 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 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 achieve our anticipated operating efficiencies at our manufacturing facility; delays or difficulties in our and our collaborators' ability to enroll patients; if our product candidates do not work as intended or cause undesirable side effects; 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, and our ability to enter into new collaboration arrangements; our current and future relationships with 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 scientific and management personnel; market and economic conditions; 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; 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, 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 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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