Precision BioSciences Receives Fast Track Designation from U.S. Food and Drug Administration for PBCAR269A, an Investigational Allogeneic CAR T Therapy for Relapsed/Refractory Multiple Myeloma

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DURHAM, N.C., Sept. 09, 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 the U.S. Food and Drug Administration (FDA) has granted Fast Track Designation to PBCAR269A for the treatment of relapsed/refractory multiple myeloma. This is the company's second allogeneic chimeric antigen receptor (CAR T) cell therapy to receive Fast Tack Designation for which the FDA previously granted Orphan Drug Designation.

"Fast Track Designation will help us expedite our allogeneic CAR T cell therapy program aimed to address the unmet medical need among patients with relapsed/refractory multiple myeloma," said Chris Heery, M.D., Chief Medical Officer of Precision BioSciences. "We look forward to working more closely with the FDA as we continue to investigate PBCAR269A as a potential new treatment option that can be more broadly available to patients who otherwise may be ineligible or unable to access existing autologous CAR T therapies."

About Fast Track Designation
Fast Track Designation facilitates the expedited development and review of a new drug, whether alone or in combination with another drug that may address unmet medical needs and treats a serious or life-threatening disease. Benefits of this designation include more frequent engagements with the FDA to discuss the drug's clinical development plan, eligibility for Accelerated Approval and Priority Review, and a Rolling Review in which Precision can submit completed sections of its New Drug Application (NDA) for review by the FDA rather than waiting to complete the NDA before it can be submitted for review.

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 is 6×10^5 CAR T cells/kg body weight with subsequent cohorts treated with escalating doses to a maximum dose of 6×10^6 CAR T cells/kg body weight. The trial is being conducted at multiple U.S. sites with clinical trial material generated in-house at the Manufacturing Center for Advanced Therapeutics (MCAT) in Durham, North Carolina. 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 that 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. This brief video illustrates the process.

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 known 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 Company's timing of, results from and information involving the Company's clinical trials involving PBCAR269A, and details of our manufacturing process 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," "designed to", "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 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, 2020, as any such factors may be updated from time to time in our other filings with the SEC, including, but not limited to, our Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2020, 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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