



Precision BioSciences Receives Fast Track Disease Designation from U.S. Food and Drug Administration for PBCAR0191 Investigational Allogeneic CAR T Cell Therapy

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DURHAM, N.C., Aug. 19, 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 Precision for PBCAR0191, the company's lead investigational allogeneic chimeric antigen receptor (CAR T) cell therapy for the treatment of advanced B-cell precursor acute lymphoblastic leukemia (B-ALL).

"Fast Track Designation is intended to fill an unmet medical need by accelerating the development of agents for patients in need of potentially better therapeutic options," said Chris Heery, MD, Chief Medical Officer of Precision BioSciences. "We continue to work toward demonstrating that PBCAR0191, as well as our other two allogeneic CAR T clinical programs, may play a role in the treatment paradigm of advanced malignancies in the future. We believe the balance of safety and efficacy plus the accessibility of allogeneic cell therapies may fill a void left by autologous CAR T therapies. This designation provides more flexibility as we attempt to identify the optimal patient population in which to seek regulatory approval."

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 PBCAR0191 Clinical Trial

PBCAR0191 is being evaluated in a Phase 1/2a multicenter, nonrandomized, open-label, parallel assignment, dose-escalation, and dose-expansion study to evaluate the safety and tolerability of PBCAR0191 in adult patients with R/R B-cell acute lymphoblastic leukemia (B-ALL) and R/R non-Hodgkin lymphoma (NHL). The NHL cohort includes patients with mantle cell lymphoma, an aggressive subtype of NHL, for which the FDA previously granted Orphan Drug Designation. PBCAR0191 is being developed in collaboration with Servier, an international pharmaceutical company. For more information, visit www.clinicaltrials.gov, study identifier number NCT03666000.

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.

About Precision's Collaboration with Servier

Under the terms of the agreement with Servier, Precision is solely responsible for early-stage research activities and Phase 1 execution for PBCAR0191, as well as preparation of clinical supply for any Phase 2 clinical trials. 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.

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 PBCAR0191, PBCAR20A and PBCAR269A, and details of our manufacturing process. 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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