Precision BioSciences Announces FDA Acceptance of IND for PBCAR269A, a BCMA Targeted Genome Edited Allogeneic CAR T Therapy Candidate for Multiple Myeloma

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-Phase 1 clinical trial of off-the-shelf (allogeneic) anti-BCMA CAR T therapy candidate for patients with relapsed/refractory multiple myeloma expected to begin dosing patients in 2020-

-PBCAR269A has received Orphan Drug Designation from the FDA for the treatment of multiple myeloma-

-First program for which clinical trial material will be generated fully in-house at Precision's Manufacturing Center for Advanced Therapeutics (MCAT) in Durham, N.C.-

DURHAM, N.C., Jan. 13, 2020 (GLOBE NEWSWIRE) -- Precision BioSciences, Inc. (Nasdaq: DTIL), a genome editing company dedicated to improving life through the application of its pioneering, proprietary ARCUS® platform, today announced that the U.S. Food and Drug Administration (FDA) has accepted its Investigational New Drug (IND) application for PBCAR269A, the Company's third allogeneic chimeric antigen receptor (CAR) T cell therapy candidate. The FDA has also granted Orphan Drug Designation to PBCAR269A for the treatment of multiple myeloma. Wholly-owned by Precision, PBCAR269A is an allogeneic CAR T therapy candidate which targets the B-cell maturation antigen (BCMA) and is in development for the treatment of relapsed/refractory multiple myeloma. Precision plans to initiate dosing in this Phase 1 clinical trial in 2020.

"FDA acceptance of the IND for PBCAR269A further underscores the ongoing progress in our allogeneic CAR T pipeline," commented Matt Kane, Chief Executive Officer of Precision BioSciences. "We have now moved three CAR T programs from preclinical to clinical stage development since April 2019, and we look forward to continuing to advance our allogeneic CAR T portfolio to bring these novel therapeutic candidates to patients. The IND for PBCAR269A builds on the initial clinical data we presented in late 2019 for our lead program, PBCAR0191, and the FDA's acceptance of the IND for our second program, PBCAR20A. It's a testament to the hard work and expertise of the Precision team that we will be able to generate the clinical trial material for the PBCAR269A trial in-house at our MCAT manufacturing facility."

"In preclinical disease models, PBCAR269A has demonstrated no evidence of graft-versus-host disease at doses that resulted in potent anti-tumor activity," commented Chris Heery, Chief Medical Officer of Precision BioSciences. "There remains significant unmet need in the treatment of relapsed/refractory multiple myeloma, and we are excited to begin clinical trials with an off-the-shelf CAR T therapy candidate in this setting."

About the PBCAR269A Clinical Trial
PBCAR269A will be evaluated in a Phase 1 multicenter, open-label dose-escalation and dose-expansion clinical trial in adult relapsed/refractory multiple myeloma patients. The trial will be conducted at multiple U.S. sites. For more information, visit www.clinicaltrials.gov, study identifier number NCT04171843.

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 by improving access to care through a well-tolerated lymphodepletion regimen, high quality cell products derived from carefully selected healthy donors, and a consistent final cell product with attributes in line with those previously observed to result in optimal safety and activity profiles. 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 in a single step, 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
Information contained in this press release contains forward-looking statements. All statements other than statements of present and historical facts contained in this press release, including without limitation, statements regarding the potential for the successful development of PBCAR269A for patients living with multiple myeloma and the timing of trials for this therapy candidate and the preliminary data therefrom, may be forward looking statements. Without limiting the foregoing, the words "anticipate," "believe," "could," "expect," "should," "plan," "intend," "estimate," "target," "may," "will," "would," "potential," the negative thereof and similar words and expressions are intended to identify forward-looking statements. These forward-looking statements reflect various assumptions of Precision's management that may or may not prove to be correct. No forward-looking statement is a guarantee of future results, performance, or achievements, and one should avoid placing undue reliance on such statements.

Forward-looking statements are based on our management's 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 factors, including, but not limited to, our ability to become profitable; our ability to procure sufficient funding; our limited operating history; our ability to identify, develop and commercialize our 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 future product candidates, and any related restrictions, limitations and/or warnings in the label of an approved product candidate; the 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; our ability to obtain and maintain intellectual property protection for our technology and any of our product candidates; the potential for off-target editing or other adverse events, undesirable side effects or unexpected characteristics associated with 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; potential liability lawsuits and penalties related to our technology, our product candidates and our current and future relationships with third parties; and other important factors discussed under the caption "Risk Factors" in our quarterly report on Form 10-Q filed for the quarterly period ended September 30, 2019, as 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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