Precision BioSciences Announces Dosing of First Patient in Off-The-Shelf CAR T Cell Therapy Phase 1/2a Clinical Trial

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First NHL patient treated with allogeneic CAR T in U.S.-based trial

DURHAM, N.C., April 17, 2019 (GLOBE NEWSWIRE) -- Precision BioSciences (Nasdaq: DTIL) ("Precision"), a genome editing company dedicated to improving life (DTIL) through its proprietary ARCUS® genome editing platform, announced today it has dosed the first patient in the Phase 1/2a clinical trial of PBCAR0191, its first gene-edited allogeneic anti-CD19 chimeric antigen receptor (CAR) T cell product candidate. Precision is developing PBCAR0191 in collaboration with Servier, an international pharmaceutical company. PBCAR0191 is made from donor-derived T cells that are modified using Precision's ARCUS genome editing technology. These edits are designed to generate CAR T cells that specifically recognize CD19, an important target in several B-cell cancers, and to prevent graft-versus-host disease, a significant complication associated with existing donor-derived cell-based therapies. This CAR T cell product candidate is being evaluated in adult patients with relapsed or refractory ("R/R") non-Hodgkin lymphoma ("NHL") or R/R B-cell precursor acute lymphoblastic leukemia (B-ALL) as an off-the-shelf cell therapy. The first patient dosed in this trial is being treated for R/R NHL, and Precision believes this is the first U.S.-based clinical trial to evaluate an allogeneic CAR T therapy for NHL.

This multi-center, open label study of PBCAR0191 is expected to enroll up to 80 patients and several dose levels of PBCAR0191 will be investigated. Clinical sites include City of Hope, Moffit Cancer Center, Dana-Farber Cancer Institute and MD Anderson Cancer Center. The primary objective of the trial is to evaluate the safety of PBCAR0191 and determine the maximum tolerated dose. Secondary objectives include evaluating the anti-tumor activity of PBCAR0191. Precision will also evaluate the expansion, trafficking and persistence of PBCAR0191 in treated patients. Lymphodepletion will be conducted several days prior to PBCAR0191 infusion. Patient outcomes will be collected for up to one year.

About Precision BioSciences

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.

About the Collaboration with Servier

Under their February 2016 partnership with Baxalta, now 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.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements other than statements of historical facts are forward-looking statements, including without limitation, the promise and potential impact of our genome editing platform and product candidate PBCAR0191. In some cases, you can identify forward-looking statements by terms such as "anticipate," "believe," "could," "expect," "should," "plan," "intend," "estimate," "target," "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 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 final prospectus filed with the SEC under Form 424(b) on March 28, 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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