Precision BioSciences Provides Updates on Azer-Cel FDA Meeting, Potential Partnerships and Timing of In Vivo R&D Day

July 27, 2023 at 7:30 AM EDT

DURHAM, N.C.--(BUSINESS WIRE)--Jul. 27, 2023-- Precision BioSciences, Inc. (Nasdaq: DTIL), a clinical stage gene editing company developing ARCUS®-based *in vivo* gene editing and *ex vivo* allogeneic CAR T therapies, today announced that it has received final meeting minutes from its recent Type B End of Phase 1 meeting with the U.S. Food and Drug Administration (FDA) for its lead investigational allogeneic CAR T therapy azercabtagene zapreleucel (azer-cel).

“The objective of our meeting with the FDA was to gain further clarity on the potential registration path for azer-cel including study design, endpoints and the recommended phase 2 dose for the CAR T relapsed patient setting – a patient population with dire need for better therapeutic options,” said Alan List, MD, Chief Medical Officer at Precision BioSciences. “We were able to accomplish the meeting objective and are appreciative of the FDA’s clear and thoughtful advice.”

The meeting with the FDA provided clarity and direction on azer-cel development, including a potential pathway toward registration. Based on the advice received from the FDA and clinical data shared during the May 2023 CAR T update, Precision is currently advancing discussions with multiple potential strategic partners for its cell therapy assets, including hematologic and non-hematologic applications.

“The ongoing collaborative discussions are intended to help us meet two key objectives: securing the right partner to build on our clinical-stage CAR T assets and allowing us to focus on core capabilities of *in vivo* gene editing,” said Michael Amoroso, Chief Executive Officer at Precision BioSciences. “We look forward to providing additional updates on our cell therapy strategic partnering initiatives as they develop.”

***In Vivo* R&D Day to be Held on September 12, 2023**

Precision will host its *in vivo* gene editing R&D Day on September 12, 2023. This presentation will be focused on providing an update on ARCUS *in vivo* gene editing candidates and the broad potential and versatility of the platform. Additionally, this timing will allow strategic partnering discussions around the *ex vivo* allogeneic cell therapies to mature and enable full investor attention on our *in vivo* gene editing pipeline.

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 precise and versatile genome editing platform that was designed with therapeutic safety, delivery, and control in mind. Using ARCUS, the Company’s pipeline consists of several *in vivo* gene editing candidates designed to cure genetic and infectious diseases where no adequate treatments exist and multiple *ex vivo* clinical candidates. 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 clinical development, expected efficacy, and benefit of our product candidates, including our ability to progress azer-cel and other product candidates towards potential registration, the expected timing of updates regarding our allogeneic CAR T and *in vivo* programs, expectations about our operational initiatives and business strategy, expectations around partnership opportunities, and the timing of our *in vivo* gene editing R&D Day. In some cases, you can identify forward-looking statements by terms such as “aim,” “anticipate,” “approach,” “believe,” “contemplate,” “could,” “estimate,” “expect,” “goal,” “intend,” “look,” “may,” “mission,” “plan,” “possible,” “potential,” “predict,” “project,” “pursue,” “should,” “target,” “will,” “would,” 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. These statements are neither promises nor guarantees, but involve 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; the risk that other genome-editing technologies may provide significant advantages over our ARCUS technology; our dependence on our ARCUS technology; the initiation, cost, timing, progress, achievement of milestones and results of research and development activities and preclinical and clinical studies; public perception about genome editing technology and its applications; competition in the genome editing, biopharmaceutical, and biotechnology fields; our or our collaborators’ ability to identify, develop and commercialize product candidates; pending and potential product 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 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; our ability to obtain orphan drug designation or fast track designation for our product candidates or to realize the expected benefits of these designations; 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; the rate and degree of market acceptance of any of our product candidates; our ability to effectively manage the growth of our operations; our ability to attract, retain, and motivate executives and personnel; effects of system failures and security breaches; insurance expenses and exposure to uninsured liabilities; effects of tax rules; effects of the COVID-19 pandemic and variants thereof, or any pandemic, epidemic, or outbreak of an infectious disease; 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; effects of natural and manmade disasters, public health emergencies and other natural catastrophic events; effects of sustained inflation, supply chain disruptions and major central bank policy actions; market and economic conditions; risks related to ownership of our common stock, including fluctuations in our stock price, 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, 2023, 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 page of our website under SEC Filings 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 have no obligation to update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise.

View source version on businesswire.com: https://www.businesswire.com/news/home/20230727013670/en/

Investor and Media Contact:
Mei Burris
Director, Investor Relations and Finance
Mei.Burris@precisionbiosciences.com

Source: Precision BioSciences, Inc.