Precision BioSciences Receives Favorable Type C Feedback from the FDA on the Company's Chemistry, Manufacturing, and Controls (CMC) Strategies for Late-Stage Development of Azercabtagene Zapreleucel, its Lead Allogeneic CAR T Clinical Candidate

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- FDA feedback signals the Company's CMC plans shared are in alignment with Agency requirements and expectations

- CMC regulatory feedback is a critical step in the pathway for development of azer-cel

DURHAM, N.C.--(BUSINESS WIRE)--Jan. 6, 2023-- Precision BioSciences (Nasdaq: DTIL), a clinical stage gene editing company developing ARCUS®-based *ex vivo* allogeneic CAR T and *in vivo* gene editing therapies, today announced that the U.S. Food and Drug Administration (FDA) provided supportive Type C feedback on the Company's CMC processes and analytical methods for azercabtagene zapreleucel (azer-cel; PBCAR0191). Azer-cel is Precision BioSciences lead allogeneic CAR T candidate being evaluated for relapsed or refractory (R/R) non-Hodgkin lymphoma (NHL) in subjects who have relapsed following autologous CAR T treatment.

"We are pleased with the FDA feedback on key components of our planned CMC package to support azer-cel ongoing development. The responses to questions regarding our analytical methods, proposed potency assays, and manufacturing processes are aligned with our expectations and help guide our plans," said Karl Whitney, Vice President and Head of Regulatory Affairs at Precision BioSciences. "We appreciate the FDA's input and look forward to continuing regulatory engagement at critical points along our development horizon."

"We look forward to continuing enrollment in the ongoing Phase 1/2a trial and working closely with the FDA as we pursue development of azer-cel. Azer-cel has the potential to become the first allogeneic CAR T therapy to reach the market," said Alan List, M.D., Chief Medical Officer at Precision BioSciences. "There are currently no FDA-approved allogeneic CAR T products to address the high unmet need of the CAR T relapsed or refractory patient population. While autologous CAR T therapy is a promising treatment option for hematological malignancies, up to 60% of high-grade NHL patients relapse after treatment and up to 20% of intended auto-CAR T patients never receive treatment due to inability to manufacture the CAR T product. An effective off-the-shelf allogeneic CAR T treatment has the potential to offer clinical benefit to this growing population of lymphoma patients."

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 multiple ex vivo "off-the-shelf" CAR T immunotherapy clinical candidates and several in vivo gene editing candidates designed to cure genetic and infectious diseases where no 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 clinical development and regulatory review of our product candidates, the expected timing of updates regarding our allogeneic CAR T programs, expected efficacy and benefit of our product candidates and programs, and expectations about our operational initiatives and our business strategy. 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," "promise," "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. 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 studies and clinical trials; 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 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 COVID-19 pandemic and variants thereof, 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 September 30, 2022, 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.

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