Precision BioSciences Announces Investigational New Drug Clearance by Partner TG Therapeutics for Investigation of Azer-Cel for Multiple Sclerosis

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- Out licensed allogeneic CAR T azer-cel receives IND clearance from U.S. FDA

DURHAM, N.C.--(BUSINESS WIRE)--Aug. 9, 2024-- Precision BioSciences, Inc. (Nasdaq: DTIL), an advanced gene editing company utilizing its novel proprietary ARCUS® platform to develop in vivo gene editing therapies for sophisticated gene edits, including gene elimination, gene insertion, and gene excision, today announced that its partner TG Therapeutics has received U.S. Food and Drug Administration (FDA) clearance for its Investigational New Drug (IND) Application to investigate Azercabtagene Zapreleucel (azer-cel) in human clinical trials for the treatment of progressive forms of multiple sclerosis. Azer-cel is an experimental allogeneic CAR T therapy discovered by Precision BioSciences and licensed to TG Therapeutics for the treatment of autoimmune diseases. TG Therapeutics anticipates commencing a phase 1 clinical trial in 2024.

“We would like to congratulate TG Therapeutics on receiving IND clearance for azer-cel in patients with progressive multiple sclerosis. We believe the expansion of allogeneic CAR T into autoimmune diseases holds the potential to unlock new therapies for patients living with chronic disease," said Michael Amoroso, Chief Executive Officer of Precision BioSciences. “We look forward to TG Therapeutics initiating a clinical trial for azer-cel in autoimmune disease as we focus on the advancement of our own wholly owned *in vivo* gene editing pipeline, including our planned IND and/or Clinical Trial Application (CTA) submission for PBGENE-HBV for hepatitis B this year.”

In January 2024, Precision BioSciences announced a licensing deal with TG Therapeutics for the CAR T therapy azer-cel. In exchange for global rights to azer-cel for automimmune diseases and indications outside of cancer, Precision received upfront and potential near-term economics valued at $17.5 million and up to $288 million in other milestone payments based on achievement of certain clinical, regulatory, and commercial milestones, in addition to high-single-digit to low-double-digit royalties on net sales.

About Precision BioSciences, Inc.

Precision BioSciences, Inc. is an advanced gene editing company dedicated to improving life (DTIL) with its novel and proprietary ARCUS® genome editing platform that differs from other technologies in the way it cuts, its smaller size, and its simpler structure. Key capabilities and differentiating characteristics may enable ARCUS nucleases to drive more intended, defined therapeutic outcomes. Using ARCUS, the Company’s pipeline is comprised of in vivo gene editing candidates designed to deliver lasting cures for the broadest range of genetic and infectious diseases where no adequate treatments exist. For more information about Precision BioSciences, please visit www.precisionbiosciences.com.

The ARCUS® platform is being used to develop in vivo gene editing therapies for sophisticated gene edits, including gene insertion (inserting DNA into gene to cause expression/add function), elimination (removing a genome e.g. viral DNA or mutant mitochondrial DNA), and excision (removing a large portion of a defective gene by delivering two ARCUS nucleases in a single AAV).

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 expected safety, efficacy and benefit of our product candidates (including azer-cel) and gene editing approaches including editing efficiency and differentiating aspects; the suitability of azer-cel for oncology indications and non-oncology indications including multiple sclerosis; the suitability of ARCUS nucleases for gene insertion, large gene deletion, and other gene editing approaches; the expected timing of regulatory processes; expectations around partnership opportunities; expectations about achievement of key milestones and receipt of any milestone, royalty, or other payments; and anticipated timing of clinical trials. 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, and involve 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 to advance our programs; risks associated with our capital requirements, anticipated cash runway, requirements under our current debt instruments and effects of restrictions thereunder, including our ability to raise additional capital due to market conditions and/or our market capitalization; our operating expenses and our ability to predict what those expenses will be; our limited operating history; the progression and 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, including clinical trial and investigational new drug applications; public perception about genome editing technology and its applications; competition in the genome editing, biopharmaceutical, and biotechnology fields; our or our collaborators’ or other licensees’ ability to identify, develop and commercialize product candidates; pending and potential product liability lawsuits and penalties against us or our collaborators or other licensees related to our technology and our product candidates; the U.S. and foreign regulatory landscape applicable to our and our collaborators’ or other licensees’ development of

product candidates; our or our collaborators' or other licensees' ability to advance product candidates into, and successfully design, implement and complete, clinical trials; potential manufacturing problems associated with the development or commercialization of any of our product candidates; delays or difficulties in our and our collaborators' and other licensees' 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 or our licensees' 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' or other licensees' 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 any pandemic, epidemic, or outbreak of an infectious disease; the success of our existing collaboration and other license 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; our ability to meet the requirements of and maintain listing of our common stock on Nasdaq or other public stock exchanges; and other important factors discussed under the caption "Risk Factors" in our Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2024, 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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