Precision BioSciences Receives U.S. and International Patent Allowances for Proprietary PCSK9 ARCUS Nuclease

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DURHAM, N.C.--(BUSINESS WIRE)--Apr. 13, 2023-- Precision BioSciences, Inc. (Nasdaq: DTIL), a clinical stage gene editing company developing ARCUS®-based *ex vivo* allogeneic CAR T and *in vivo* gene editing therapies, today announced it has received a Notice of Allowance from the U.S. Patent and Trademark Office (USPTO) for U.S. Patent Application No. 16/606,856, titled "Engineered meganucleases specific for recognition sequences in the PCSK9 gene." Corresponding international applications in this family have also been allowed in Europe, Australia, Mexico, Japan, and Israel since October 2022. Once issued, patents arising from these international applications will have standard expiration dates in October 2038, and the U.S. patent arising from the '856 application will have a standard expiration date in August 2040.

The allowed composition of matter claims in these U.S. and international applications encompass a PCSK9-specific ARCUS nuclease. This ARCUS nuclease has been used preclinically for both gene deletion approaches for cardiovascular diseases such as familial hypercholesterolemia (FH) and, as importantly, a viable and safe site to insert a functional copy of a specific gene to restore function addressing other diseases requiring gene addition.

"Due to their unique properties and Precision's state-of-the-art engineering process, ARCUS nucleases are exceptionally well-suited for many hard-to-treat genetic conditions requiring gene insertion or addition and large gene excisions. These types of gene edits may be too complex for other gene editing technologies at the editing efficiencies needed for therapeutic benefit," said Jeff Smith, Co-Founder and Chief Research Officer at Precision BioSciences. "These patents further strengthen our intellectual property portfolio on our PCSK9 ARCUS nucleases which provide us with the potential capability and optionality to target the well-characterized PCSK9 gene for gene deletion through partnerships in cardiovascular diseases, such as familial hypercholesterolemia, as well as provide us the potential ability to more rapidly pioneer therapeutic gene insertion strategies for Precision's own organic pipeline."

"As a result of their distinctive editing mechanism and novel features, we believe ARCUS nucleases are characterized by their safety, high efficiency gene editing and ability to be distributed to a variety of targeted tissues by either lipid nanoparticle or AAV," said Michael Amoroso, Chief Executive Officer. "Precision, either alone or with world-class partners, such as Novartis, Lilly and iECURE, has active *in vivo* gene editing programs for targeted gene insertion and gene excisions in hematopoietic stem cells, liver, muscle and the central nervous system showcasing the distinctive versatility of ARCUS."

In 2023, Precision expects to host an *in vivo* gene editing R&D event and present new preclinical data in Duchenne muscular dystrophy and hepatitis B. In addition, iECURE is targeting to file a CTA and/or IND for a product incorporating the Precision PCSK9 nuclease for ornithine transcarbamylase (OTC) deficiency in the second half of 2023.

About ARCUS and "Safe harbor" ARCUS Nucleases

ARCUS is a proprietary genome editing technology discovered and developed by scientists at Precision BioSciences. It uses sequence-specific DNA-cutting enzymes, or nucleases, that are designed to either insert (knock-in), excise (knock-out), or repair DNA of living cells and organisms. ARCUS is based on a naturally occurring genome editing enzyme, I-CreI, that evolved in the algae Chlamydomonas reinhardtii to make highly specific cuts in cellular DNA and stimulate gene insertion at the cut site by homologous recombination. Precision's platform and products are protected by a comprehensive portfolio including nearly 100 patents to date.

Precision can use an ARCUS nuclease to add a healthy copy of a gene (or "payload") to a person's genome. The healthy copy of the gene can be inserted at its usual site within the genome, replacing the mutated, disease-causing copy. Alternatively, an ARCUS nuclease can be used to insert a healthy copy of the gene at another site within the genome called a "safe harbor" that enables production of the healthy gene product without otherwise affecting the patient's DNA.

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. The Company intends such forward-looking statements to be covered by the safe harbor provisions for forward-looking statements contained in Section 27A of the Securities Act and Section 21E of the Exchange Act. 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 expected safety, efficacy, and benefit of our gene editing approaches including editing efficiency and delivery methods, the suitability of ARCUS nucleases for gene insertion, large gene deletion, and

other complex gene editing approaches and the utilization of safe harbor site strategies for therapeutic gene insertion. The words “aim,” “anticipate,” “approach,” “believe,” “contemplate,” “could,” “estimate,” “expect,” “goal,” “intend,” “look,” “may,” “mission,” “plan,” “possible,” “potential,” “predict,” “project,” “promise,” “pursue,” “should,” “target,” “will,” “would,” and other similar words or expressions, or the negative of these words or similar words or expressions, are intended to identify forward-looking statements, though not all forward-looking statements use these words or 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; our dependence on our ARCUS technology; the risk that other genome-editing technologies may provide significant advantages over 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 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; 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; effects of sustained inflation, supply chain disruptions and major central bank policy actions; 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 Annual Report on Form 10-K for the annual period ended December 31, 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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