Precision BioSciences Announces U.S. Patent Covering PBGENE-HBV for Chronic Hepatitis B and Updates Program Status

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- Strengthens the Company's intellectual property portfolio for lead in vivo program PBGENE-HBV with U.S. patent protection into 2042-

- Phase 1 ELIMINATE-B trial progressing through clinical investigation with dosing of Cohort 3 initiated in Third Quarter of 2025-

DURHAM, N.C.--(BUSINESS WIRE)--Sep. 8, 2025-- Precision BioSciences, Inc. (Nasdaq: DTIL), a clinical stage gene editing company utilizing its novel proprietary ARCUS® platform to develop *in vivo* gene editing therapies for diseases with high unmet need, today announced that it will be issued U.S. Patent No. 12,410,418 by the U.S. Patent and Trademark Office on September 9, 2025, titled "Optimized engineered meganucleases having specificity for a recognition sequence in the Hepatitis B Virus genome." The composition of matter claims in this U.S. patent will encompass the PBGENE-HBV ARCUS nuclease utilized in the Company's lead *in vivo* gene editing program, which recognizes a highly conserved target sequence present in both HBV covalently closed circular DNA (cccDNA) and integrated HBV DNA. This U.S. patent will have an expiration date in March 2042. The Company was granted patents in Europe and Hong Kong earlier this year with similar composition of matter claims.

"As the ELIMINATE-B trial for PBGENE-HBV continues to advance, we are pleased that this newly issued U.S. patent, alongside our granted patents in Europe and Hong Kong, will significantly reinforce our intellectual property portfolio covering PBGENE-HBV, our lead product candidate aimed at transforming the treatment of chronic hepatitis B," said Michael Amoroso, President and Chief Executive Officer at Precision BioSciences. "A key objective of the trial is the ability to safely escalate the dose. In Q3 2025, while continuing to safely administer repeat doses in Cohort 2, we initiated dosing patients in Cohort 3 in the Phase 1 ELIMINATE-B trial. This supports our therapeutic strategy of finding the right dose and schedule, defined as number of administrations and time interval between dosing, to drive complete cures for patients with chronic Hepatitis B. We remain on track to provide further data updates in 2025."

About PBGENE-HBV (Viral Elimination Program):

PBGENE-HBV is Precision's wholly owned *in vivo* gene editing program under investigation in a global first-in-human clinical trial, which is designed to potentially cure chronic hepatitis B infection. Currently, it is estimated that 300 million people worldwide are afflicted with chronic hepatitis B. PBGENE-HBV is the first and only potentially curative gene editing program to enter clinical investigation that is specifically designed to eliminate cccDNA and inactivate integrated HBV DNA. Lipid nanoparticle technology for PBGENE-HBV has been provided by Acuitas Therapeutics Inc.

About the ELIMINATE-B Trial:

The Phase 1 ELIMINATE-B study is currently enrolling HBeAg-negative chronic hepatitis B patients at world-class sites in Moldova, Hong Kong, and New Zealand, and imminently commencing in the U.S. The goal of the study is to define the optimal dose and number of dose administrations for safely eliminating cccDNA and inactivating integrated HBV DNA. With regulatory approval already granted, Precision expects to expand the study to clinical trial sites in the U.S. and U.K. and continue accelerating recruitment and evaluation of a genetically diverse patient population in the Phase 1 study.

About Precision BioSciences, Inc.

Precision BioSciences, Inc. is a clinical stage 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 such as in the DMD program).

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 key advantages of ARCUS and its key capabilities and differentiating characteristics; expectations about operational initiatives, strategies, further development, or timing of additional updates or data releases of PBGENE-HBV, including timing of dose administrations and subsequent cohorts in the ELIMINATE-B trial and data updates in 2025 and beyond; and the unique design of PBGENE-HBV to eliminate cccDNA and inactivate integrated HBV DNA with high specificity. In some cases, you can identify forward-looking statements by terms such as "aim," "anticipate," "approach," "believe," "contemplate," "could," "design," "designed," "estimate," "expect," "goal," "intend," "look," "may," "mission," "plan," "possible," "potential," "predict," "project," "pursue," "should," "strive," "suggest," "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, 2025, 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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