Precision BioSciences Announces Opening of First Clinical Trial Site in U.S. for ELIMINATE-B Trial

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- Massachusetts General Hospital, Harvard Medical School, actively recruiting chronic hepatitis B patients along with multiple global clinical trial sites -

- Phase 1 ELIMINATE-B trial for PBGENE-HBV is progressing and on track to report additional data from higher dose cohorts in 2025 -

DURHAM, N.C.--(BUSINESS WIRE)--Oct. 7, 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 high unmet need diseases, today announced the activation of its first U.S. clinical trial site to evaluate PBGENE-HBV as part of the ELIMINATE-B Phase 1 clinical trial. The newly activated site at Massachusetts General Hospital in Boston, Massachusetts, is now actively recruiting patients.

“Chronic hepatitis B remains one of the most pressing global health challenges with millions of patients facing risk of liver disease progression to cirrhosis and liver cancer,” said Cindy Atwell, Chief Development and Business Officer at Precision BioSciences. “As we continue to advance our ELIMINATE-B trial through Cohort 3, we are thrilled to open recruitment at Massachusetts General Hospital, a world-renowned institution with deep expertise in running clinical studies in hepatitis. Initiation of our first U.S. trial site represents an important step in expanding our study to patients in the United States. Looking ahead, we remain on track to provide further data updates on the ELIMINATE-B study in 2025.”

The Phase 1 ELIMINATE-B study is an open-label, multi-part study designed to evaluate the safety and tolerability of PBGENE-HBV with the goal to define the optimal dose, number of dose administrations and dosing interval necessary to drive complete cures for patients with chronic hepatitis B.

Investigators at Massachusetts General Hospital are committed to advancing innovative research in chronic hepatitis B and look forward to enrolling patients in the ELIMINATE-B trial which represents an opportunity to evaluate a novel gene-editing approach that directly targets the virus at its source.

Precision BioSciences is actively recruiting patients. For more information on the trial including patient eligibility, study sites and contact details, please visit clinicaltrials.gov using identifier NCT06680232.

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 Hepatitis B:

Hepatitis B is a leading cause of morbidity in the US and death globally, with no curative options currently available for patients. Despite the availability of approved antiviral therapies, an estimated 300 million people globally and 1-2 million people in the US are estimated to have chronic hepatitis B infection. An estimated 15% to 40% of patients with HBV infections may develop complications, such as cirrhosis, liver failure, or liver cancer (hepatocellular carcinoma), which account for the majority of HBV-related deaths.

Chronic hepatitis B infection is primarily driven by persistence of HBV cccDNA, which enables continued viral replication, and integration of HBV DNA into the human genome in liver cells. Current treatments for patients with chronic hepatitis B include agents that result in long-term viral suppression as indicated by reduction of circulating HBV DNA, but these therapies do not eradicate HBV cccDNA, rarely lead to functional cure, and require lifelong administration.

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, New Zealand, and 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.K. and continue accelerating recruitment and evaluation of a genetically diverse patient population in the Phase 1 study.

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, expectations about operational initiatives, strategies, further development, or timing of additional updates or data releases of PBGENE-HBV, including being on track to report additional data from higher dose cohorts in 2025; the goal of the Phase I ELIMINATE-B study to define the optimal dose, number of dose administrations and dosing interval necessary to drive complete cures for patients with chronic hepatitis B; and PBGENE-HBV as a novel gene editing approach that directly targets the virus at its source. In some cases, you can identify forward-looking statements by terms such as “aim,” “anticipate,” “approach,” “belief”, “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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