Precision BioSciences Announces Presentation of Initial Safety Data from the Phase 1 ELIMINATE-B Trial Evaluating PBGENE-HBV at the 2025 European Association for the Study of the Liver Congress (EASL)

May 7, 2025 at 7:01 AM EDT

DURHAM, N.C.--(BUSINESS WIRE)--May 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 diseases with high unmet need, today announced that it will present initial safety data from the Phase 1 ELIMINATE-B trial evaluating PBGENE-HBV program for the treatment of chronic hepatitis B during a late breaking poster presentation at the European Association for the Study of the Liver (EASL) Congress being held May 7-10, 2025, in Amsterdam, Netherlands.

“We are pleased to share initial safety data from the ELIMINATE-B trial for PBGENE-HBV at this year’s EASL congress. Since initiating the trial, we have made rapid progress activating global clinical sites and enrolling patients as we seek to validate our ARCUS-elimination approach in the clinic for chronic hepatitis B,” said Michael Amoroso, President and Chief Executive Officer at Precision BioSciences. “This initial safety dataset across the first three patients receiving repeat administrations (two doses) as planned in the ELIMINATE-B protocol provide early validation of the translation of preclinical pharmacokinetic and safety data in patients. We are encouraged by the signals we are seeing in the study thus far and believe these data continue to support multiple dose administrations of PBGENE-HBV as well as ongoing dose escalation. This new data builds on the update shared in February and we look forward to continuing to enroll patients in the ELIMINATE-B trial and sharing further updates, including antiviral efficacy data upon completion of each cohort, three dose administrations at each dose level, throughout 2025.”

Presentation Details:

Title: Initial safety data from ELIMINATE-B, the first clinical trial of a gene editing treatment for chronic hepatitis B
Session: Late Breaker Posters
Poster Number: LBP-038
Date: Late breaker posters will be displayed from May 7-10

PBGENE-HBV is Precision’s first-in-class gene editing therapy for chronic hepatitis B being evaluated in the global Phase 1 ELIMINATE-B study. ELIMINATE-B participants are Hepatitis B e-antigen negative with chronic hepatitis B and virologically suppressed on nucleos(t)ide analog (NA) treatment. Initial study participants were enrolled at a study site in Moldova. The first cohort comprised of three participants, all of whom were male with a mean age of 41 years and range of 5.9-7.2 years on NA treatment. The participants varied in their duration of infection, from 7.5 to 39 years, and their baseline HBsAg levels, which were between 561 and 11,813 IU/mL. The three participants received dose level 1 (0.2 mg/kg) and have received 2 of the 3 dose administrations. PBGENE-HBV was well-tolerated upon repeat dosing, with no dose limiting toxicities, serious adverse events, or clinically significant laboratory abnormalities. All adverse events were mild (grade 1 or 2) and transient in nature, and there were no cumulative adverse events with a second dose administration. Initial safety data from the first cohort indicates the translation of PBGENE-HBV nonclinical pharmacokinetic and safety data from non-human primates into the clinic and supports pre-planned repeat dosing as well as dose escalation of PBGENE-HBV with the goal of moving appropriate dose and schedule into Phase 2 expansion.

In April 2025, the FDA granted Fast Track designation to PBGENE-HBV for chronic hepatitis B. Precision is approved for clinical investigation of its Phase 1 ELIMINATE-B trial in the United States, Moldova, Hong Kong, New Zealand, and the United Kingdom. The Company plans to continue sharing updates on full dose cohorts at all dose levels throughout 2025.

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 up to 2.4 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 and integration of HBV DNA into the human genome in liver cells, the primary source of hepatitis B surface antigen (HBsAg) in late-stage disease. Current treatments for patients with HBV infection 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 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).

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 PBGENE-HBV and our gene editing approaches, and the suitability of ARCUS nucleases for sophisticated gene edits and diseases with high unmet need; the expected timing of regulatory processes and clinical operations, including filings, studies, enrollment and clinical data for PBGENE-HBV; the encouraging early safety signals observed in the ELIMINATE-B clinical trial that support ongoing dose escalation and multiple dose administrations of PBGENE-HBV; plans to provide ongoing updates on the full low-dose cohort for the PBGENE-HBV study, including multiple dose administrations, and data from higher dose levels throughout 2025; and anticipated timing of clinical data . In some cases, you can identify forward-looking statements by terms such as “aim,” “anticipate,” “appear,” “approach,” “believe,” “contemplate,” “could,” “designed,” “encouraged”, “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 Annual Report on Form 10-K for the year ended December 31, 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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