Precision BioSciences Receives Approval in Hong Kong to Expand PBGENE-HBV Phase 1 ELIMINATE-B Trial for the Treatment of Chronic Hepatitis B

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- Approval in Hong Kong marks the first clinical trial application clearance of an in vivo gene editing approach for chronic hepatitis B in Hong Kong and the second CTA approval for PBGENE-HBV in 2024

- ELIMINATE-B is a global, multi-site study now actively recruiting patients; expected to report clinical data as it matures throughout 2025

- U.S. investigational new drug (IND) anticipated in 2025

DURHAM, N.C.--(BUSINESS WIRE)--Dec. 18, 2024-- 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 sophisticated gene edits, today announced that it has received Clinical Trial Application (CTA) approval in Hong Kong to study PBGENE-HBV in the ongoing ELIMINATE-B Phase I trial. PBGENE-HBV is Precision's lead wholly owned *in vivo* gene editing program designed to cure chronic hepatitis B by eliminating cccDNA, the key source of replicating hepatitis B virus (HBV), and inactivating integrated HBV DNA in hepatocytes. The company is actively recruiting patients for the ELIMINATE-B trial in Moldova and has begun activating a top infectious disease clinical site in Hong Kong as part of its global regulatory and clinical operations strategy.

"We are pleased to receive our second CTA approval for PBGENE-HBV, expanding our ELIMINATE-B trial into a world-class HBV clinical trial site in Hong Kong," said Dr. Murray Abramson, Senior Vice President, Head of Clinical Development of Precision BioSciences. "PBGENE-HBV has been designed to target a viral site that is prevalent across all HBV genotypes, including in Asia, and we believe that this will enable us to evaluate and provide access to as many patients as possible. In addition to Hong Kong, our clinical trial site in Moldova continues to execute as planned, and we look forward to sharing clinical data as it matures throughout 2025."

"Over 400,000 individuals in Hong Kong are currently living with chronic hepatitis B, and many patients continue to develop liver cancer or cirrhosis even on existing long-term treatment with standard of care treatments," said Dr. MF Yuen, DSc, MD, PhD, Chair Professor of Gastroenterology and Hepatology, Li Shu Fan Medical Foundation and Professor in Medicine, The University of Hong Kong. "By targeting and eliminating covalently closed circular (ccc) DNA, the root cause of the disease, PBGENE-HBV has the potential to completely eliminate the source of viral replication from the body, not just reduce it, which could transform the treatment landscape for patients in Hong Kong and millions of others worldwide. Our field has long searched for a novel way to eliminate the root cause of chronic hepatitis B, the cccDNA, and I look forward to further investigating PBGENE-HBV in clinic."

Through its precision cutting, compact design, and simple structure, PBGENE-HBV is engineered to target the HBV viral genome and drive functional cures for patients with chronic hepatitis B. PBGENE-HBV leverages the ARCUS® gene editing platform by delivering an ARCUS nuclease-encoding mRNA to the liver via lipid nanoparticles. The ARCUS nuclease specifically cuts a highly conserved sequence in the hepatitis B viral genome and is designed to eliminate the root cause of the disease, cccDNA, and inactivate integrated HBV genomes. The ARCUS platform is derived from a naturally occurring enzyme and has been optimized for over 20 years into a ground-breaking and highly precise gene editing tool.

Precision has submitted multiple global clinical trial applications and remains on track for a U.S. IND in 2025 as part of its global Phase 1 regulatory strategy for PBGENE-HBV. The company will provide updates as it receives additional regulatory approvals to begin treating patients in those markets.

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. In 2019, despite the availability of approved antiviral therapies, an estimated 300 million people globally and more than 1 million people in the US were 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 PBGENE-HBV:

PBGENE-HBV is a potentially curative approach to treating patients with chronic HBV infection through a highly specific, novel therapeutic approach. PBGENE leverages the ARCUS® platform and is designed to directly eliminate cccDNA and inactivate integrated HBV DNA with high specificity, potentially leading to functional cures.

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 our product candidates (including PBGENE-HBV); the unique design of PBGENE-HBV to eliminate cccDNA and inactivate integrated HBV DNA with high specificity, potentially leading to functional cures; the expected timing of regulatory processes (including filings such as IND's and CTA's for PBGENE-HBV and the acceptance of these filings by regulatory agencies); the suitability of PBGENE-HBV for the treatment of hepatitis and the targeting of the root cause of the disease; the key advantages of ARCUS and its key capabilities and differentiating characteristics ; expectations about operational initiatives, strategies, and further development of PBGENE-HBV; and anticipated timing of patient dosing and clinical data. In some cases, you can identify forward-looking statements by terms such as "aim," "anticipate," "approach," "believe," "contemplate," "could," "design", "designed," "endeavor," "engineered," "estimate," "expect," "goal," "intend," "look," "may," "mission," "plan," "possible," "potential," "predict," "project," "pursue," "should," "strive," "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 September 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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