Precision BioSciences Announces Late-Breaking PBGENE-HBV Data at AASLD The Liver Meeting® 2026 Further Demonstrating cccDNA Elimination and Potential to Drive Viral Cure

November 5, 2026 at 7:00 AM EST

-Phase 1 ELIMINATE-B study successful, PBGENE-HBV Program Advancing to Phase 2-

-PBGENE-HBV achieves target product profile at 0.4 mg/kg dose-

-PBGENE-HBV achieved pgRNA loss to undetectable in 100% of evaluable patients at expected go-forward dose of 0.4 mg/kg; Durable and ongoing pgRNA loss in 100% of patients with ≥6 months of follow-up-

-In hard-to-treat patient population: HBeAg-positive patient achieved a 100% pgRNA loss to undetectable from a baseline of 3.7-log copies/mL at 0.4 mg/kg dose, patient's pgRNA remained undetectable at data cut-off-

-Reproducible liver biopsy findings: PBGENE-HBV demonstrated a 1-log and 1.5-log reduction in cccDNA at 0.4 mg/kg the expected go forward dose across multiple patients-

-Treatment effect observed in 100% of evaluable patients as measured by HBsAg reduction-

-PBGENE-HBV demonstrated a well-characterized and manageable safety profile across 59 administrations in 25 patients, with no dose-limiting toxicities-

-Company to host investor and KOL webcast on Monday, November 9, 2026, at 8:00 a.m. ET presenting the late-breaking AASLD Phase 1 data-

DURHAM, N.C.--(BUSINESS WIRE)--Nov. 5, 2026-- 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 new and updated Phase 1 clinical data from the ongoing ELIMINATE-B study of PBGENE-HBV to be presented in a late-breaking oral presentation on Sunday, November 8 at 2:15pm MST, at the American Association for the Study of Liver Diseases (AASLD) The Liver Meeting® 2026. PBGENE-HBV is the first and only *in vivo* gene editing therapy designed to eliminate the root cause of chronic hepatitis B, covalently closed circular DNA (cccDNA), to drive viral cure measured by sustained undetectable HBV DNA.

The oral presentation will be delivered by our ELIMINATE-B lead investigator, Man Fung Yuen, MD, Ph.D., Chair Professor of The University of Hong Kong and the Chief of the Division of Gastroenterology and Hepatology, Queen Mary Hospital. The presentation features new and updated data from 25 patients across 59 administrations in the Phase 1 ELIMINATE-B trial. A copy of the presentation will be available on the Company's website following Dr. Yuen's oral presentation.

"The new clinical data from ELIMINATE-B represent a breakthrough in our efforts to address the underlying cause of chronic hepatitis B, cccDNA," said Michael Amoroso, President and Chief Executive Officer of Precision BioSciences. "The consistency of the findings at the 0.4 mg/kg dose, including complete and durable pgRNA loss to undetectable levels, reproducible liver biopsies demonstrating evidence of cccDNA elimination, and a treatment effect in all patients with a manageable safety profile, supports advancement to a global Phase 2 study. In the Phase 2 study, we plan to evaluate cure rates after a finite course of treatment and cessation of nucleos(t)ide analogs. Patients have long desired a cure for their virus and living a life free from daily medication - today's data is a step in that direction."

AASLD Presentation Shows Evidence of cccDNA Elimination and Favorable Safety Profile at 0.4 mg/kg

As of the data cutoff date, September 28, 2026, 25 patients had received a total of 59 administrations of PBGENE-HBV across four dose levels.

"We're thrilled to share the complete and durable loss of pgRNA in 100% of evaluable patients at our go-forward dose of 0.4 mg/kg, as well as durable, ongoing pgRNA loss in all patients who had at least 6-months of follow up, which we believe is indicative of permanent elimination of cccDNA in the liver. In total, across all dose levels, 11 evaluable patients achieved pgRNA loss to undetectable and remained undetectable through data cut off. The highlight of the data was demonstrating pgRNA loss to undetectable levels in our first HBeAg positive patient dosed on study, indicating potent effect of PBGENE-HBV in a patient population that is very difficult to treat due to logarithmically higher amounts of cccDNA and viral load in the liver," said Cassie Gorsuch, PhD, Chief Scientific Officer of Precision BioSciences.

Consistent pgRNA loss to undetectable in evaluable patients

Among 12 evaluable patients with detectable pregenomic RNA (pgRNA) at baseline, 11 (92%) achieved undetectable pgRNA following treatment with PBGENE-HBV, including all six evaluable patients at 0.4 mg/kg. The remaining patient, dosed with only two administrations at 0.65 mg/kg, experienced a 95% reduction in pgRNA at the time of the data cutoff and will continue to be followed to evaluate pgRNA at go forward visits. In groundbreaking data, the first HBeAg-positive patient treated in the study achieved undetectable pgRNA upon the second administration of PBGENE-HBV at 0.4 mg/kg, declining from 5,750 copies/mL at baseline. As a blood-based biomarker of cccDNA transcription, pgRNA provides evidence of PBGENE-HBV's intended mechanism of cccDNA elimination in the liver.

Durable pgRNA loss to undetectable sustained over time

Among patients who achieved undetectable pgRNA and had at least six months of follow-up, 100% maintained undetectable pgRNA through the data cutoff. The longest observed duration of pgRNA loss now approaches one year, extending the findings reported in May 2026. The sustained absence of detectable pgRNA across patients provides validation evidence and confidence that as designed, PBGENE-HBV is eliminating the cccDNA viral reservoir that drives chronic hepatitis B.

Reproducible liver biopsy evidence of cccDNA elimination at 0.4 mg/kg

Paired liver biopsies from two patients treated with PBGENE-HBV at 0.4 mg/kg, the go forward Phase 2 dose demonstrated approximately 1-log (10-fold) and 1.5-log (35-fold) reductions in cccDNA , respectively across multiple patients. These findings reproduce and extend the initial liver biopsy evidence of cccDNA elimination reported previously at EASL 2026. The concordance between elimination of cccDNA-derived transcripts in liver tissue and loss of circulating pgRNA provides additional evidence supporting PBGENE-HBV's intended mechanism of directly targeting and eliminating the persistent cccDNA viral reservoir responsible for chronic hepatitis B infection.

HBsAg reductions observed across all evaluable patients

All 24 evaluable patients experienced reductions in the secondary biomarker hepatitis B surface antigen (HBsAg) following treatment with PBGENE-HBV at all dose levels. Maximal HBsAg reductions approached 94% at 0.4 mg/kg, with similar antiviral activity observed in patients with and without detectable pgRNA at baseline. HBsAg is produced from both cccDNA and integrated HBV DNA, therefore elimination of cccDNA is expected to result in sustained and durable reduction of HBsAg. The HBsAg findings provide consistent supportive evidence of antiviral activity across a broad patient population and, together with pgRNA loss and liver biopsy findings, further support PBGENE-HBV's intended mechanism of action and the expected go-forward dose.

Well-characterized safety and tolerability profile with no dose-limiting toxicities

PBGENE-HBV demonstrated a well-characterized and manageable safety profile across 59 administrations in 25 patients, with no dose-limiting toxicities (DLTs) observed. The most common adverse events were infusion-related reactions consistent with lipid nanoparticle (LNP) effects, with onset and resolution generally occurring within 24 hours of infusion. The 0.4mg/kg dose was better tolerated than the 0.65mg/kg, dose, allowing all dose administrations to be delivered and further supporting the go-forward dose in Phase 2. At the expected Phase 2 dose of 0.4 mg/kg, no serious adverse events (SAEs) have been observed. Under the current infusion protocol designed to mitigate potential LNP-related inflammatory responses, no Grade 3 or higher hypotension events have occurred across 15 administrations in eight patients at the Phase 2 dose of 0.4 mg/kg.

Transient, reversible elevations in alanine aminotransferase (ALT) and aspartate aminotransferase (AST) have been observed following PBGENE-HBV administration, consistent with LNP-associated effects. These laboratory abnormalities were asymptomatic, with no associated elevations in bilirubin, cases of Hy's Law or evidence of hepatic synthetic dysfunction across any dose level. At 0.4 mg/kg under the current infusion protocol, one delayed ALT/AST elevation was observed following the third administration, with peak ALT of 306 U/L and AST of 278 U/L. The elevation was transient and resolved to normal with no intervention required and no associated bilirubin changes were observed. Collectively, the antiviral activity and safety profile of PBGENE-HBV support selection of 0.4 mg/kg for further evaluation in Phase 2.

Next Steps and Expected Milestones

“For patients with chronic hepatitis B, the persistent viral reservoir remains the central obstacle to achieving a cure,” said Dr. Man-Fung Yuen, lead investigator of the ELIMINATE-B study. “Reproducing the liver biopsy evidence of cccDNA elimination in a second patient treated at 0.4 mg/kg, together with durable pgRNA loss in patients with longer follow-up, is particularly important because it links the intended mechanism of action, cccDNA elimination, to ongoing antiviral activity. These findings provide a meaningful foundation for Phase 2 testing and for assessing whether directly targeting cccDNA can ultimately enable patients to stop long-term suppressive therapy and achieve cure.”

Based on the Phase 1 ELIMINATE-B findings, Precision has selected 0.4 mg/kg as the go-forward dose for PBGENE-HBV and is initiating a global ELIMINATE-B2 Phase 2 study. The study is designed to evaluate PBGENE-HBV as both a monotherapy and in combination with an antisense oligonucleotide (ASO), to assess its potential to achieve viral and functional cures in patients with chronic hepatitis B.

Precision is finalizing the Phase 2 protocol and onboarding clinical sites globally. The Company expects to initiate dosing in the ELIMINATE-B2 Phase 2 study in the first quarter of 2027, with enrollment planned across multiple continents. Precision anticipates generating initial open-label data from the Phase 2 study in the second half of 2027.

Conference Call Details

The webcast link for Precision’s investor update on Monday, November 9th at 8:00 AM ET can be found **here**. A replay of the presentation will be available on the Company’s Investor Relations Events and Presentations webpage following the event.

About PBGENE-HBV (Hepatitis B cccDNA Elimination Program):

PBGENE-HBV is Precision’s wholly owned *in vivo* gene editing program being evaluated in ELIMINATE-B, a global clinical trial, as a potential viral cure for chronic hepatitis B. PBGENE-HBV is the only clinical stage program that targets and eliminates covalently closed circular DNA (cccDNA), the sole source of viral replication, leading to undetectable sustained loss of pregenomic RNA (pgRNA), the precursor for HBV DNA infectious particles. PBGENE-HBV is the first and only *in vivo* gene elimination approach to prospectively employ repeat lipid nanoparticle (LNP) administration in chronic hepatitis B with the goal of viral cure, as measured by sustained undetectable HBV DNA off nucleos(t)ide therapy. The FDA has previously provided guidance that undetectable HBV DNA is the validated endpoint for chronic hepatitis B. PBGENE-HBV has been granted Fast Track designation by the FDA.

Further details on the trial can be found on Precision’s website and on **clinicaltrials.gov** under identifier NCT06680232.

About Hepatitis B:

Chronic hepatitis B viral (HBV) infection causes inflammation and damage to the liver, leading to increased risk of death from liver cancer or cirrhosis.

To date, there is no cure for chronic hepatitis B as current treatments do not result in a viral cure due to persistence of cccDNA in the liver. In patients with chronic hepatitis B, cccDNA, which contains the full-length viral genome, persists long term, produces pgRNA, and is the sole source of new infectious viral particles known as HBV DNA.

Since cccDNA is the only source of infectious particles known as HBV DNA, Precision's clinical development goals are centered around the elimination of cccDNA potentially resulting in a viral cure of chronic hepatitis B. Sustained loss of HBV DNA as a result of cccDNA elimination is the validated FDA approval endpoint for finite curative treatment and goal for the PBGENE-HBV target product profile.

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. These features are intended for ARCUS nucleases to drive more defined therapeutic outcomes. Using ARCUS, the Company's pipeline is comprised of clinical stage *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 gene elimination (removing a viral genome e.g. viral DNA such as in the Company's PBGENE-HBV program), gene excision (removing a large portion of a defective gene by delivering two ARCUS nucleases in a single AAV such as in the Company's PBGENE-DMD program), and gene insertion (inserting DNA into a gene to cause expression or add function).

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 the goal of PBGENE-HBV of viral cure as measured by sustained undetectable HBV DNA off nucleos(t)ide therapy; expectations around durable pgRNA loss in both HBeAg positive and negative patients being treated with PBGENE-HBV supporting a path towards viral cure; the potential and expected safety, efficacy, durability, and benefit of PBGENE-HBV, including the durability of pgRNA loss; the ability to advance to a global Phase 2 ELIMINATE-B trial and timing and progress of the study; belief that elimination of cccDNA could result in a viral cure of chronic hepatitis B; and the expectation that sustained loss of HBV DNA is a validated endpoint for the FDA and highly relevant for PBGENE-HBV. 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," "toward," "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 annual period ended December 31, 2025 and Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2026, 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.

View source version on businesswire.com: https://www.businesswire.com/news/home/20261105643191/en/

Investor and Media Contact:
Naresh Tanna
Chief Financial Officer
naresh.tanna@precisionbiosciences.com

Source: Precision BioSciences, Inc.