Precision BioSciences Expands ELIMINATE-B Trial Following Clinical Trial Application Approval in Two European Countries

April 15, 2026 at 7:01 AM EDT

- France and Romania planned for inclusion in the global ELIMINATE-B trial supporting broader patient enrollment -

DURHAM, N.C.--(BUSINESS WIRE)--Apr. 15, 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 that it has received Clinical Trial Application (CTA) approval to expand the ongoing global ELIMINATE-B clinical trial of PBGENE-HBV. The regulatory authorization will allow Precision to initiate important hepatitis B clinical trial sites in France and Romania. This expansion broadens the trial's global footprint deeper into Europe, adding to existing clinical trial sites in the United Kingdom, Moldova, New Zealand, Hong Kong and the United States.

The Company expects the addition of clinical trial sites in France and Romania to support continued patient enrollment and clinical execution in ELIMINATE-B with the goal to treat as many clinical trial patients as possible with PBGENE-HBV. Site initiation activities are underway, with initial patient screening expected in Q2 2026.

"Expanding ELIMINATE-B into hepatitis sites in France and Romania is an important step in the continued development of PBGENE-HBV, the only gene editing therapy uniquely designed to eliminate cccDNA," said Cindy Atwell, Chief Development and Business Officer of Precision BioSciences. "Given the strong investigator interest in PBGENE-HBV, especially following the late breaker oral presentation at The Liver Conference 2025, these new trial sites will build on our existing global clinical trial footprint as we advance PBGENE-HBV through the ELIMINATE-B trial."

About Chronic Hepatitis B

Chronic hepatitis B virus causes inflammation and damage to the liver, leading to chronic infection and increased risk of death from liver cancer or cirrhosis. There is no cure for chronic hepatitis B, and current treatments rarely result in a functional cure, primarily due to persistence of viral DNA in the liver. In patients with chronic hepatitis B, genetic material of the virus is converted within infected liver cells into cccDNA that acts as the only template to make new infectious viral particles. Hepatitis B virus also inserts fragments of its DNA into the human genome of infected liver cells. These integrated fragments are viral replication incompetent and cannot produce new infectious virus. Both cccDNA and integrated HBV DNA produce the viral protein, hepatitis B surface antigen ("HBsAg"), which is secreted into the blood.

Historically, the focus for drug development and regulatory approval of drugs for chronic hepatitis B has relied on the suppression of HBsAg. Achieving undetectable HBsAg may lead to a functional cure if there is no rebound in HBV DNA or HBsAg after drug treatment has been discontinued for at least six months, but this is achieved in less than three out of 100 patients treated with the current standard of care. Since cccDNA is the only source of infectious particles (HBV DNA), we believe that elimination of cccDNA could result in a cure of chronic hepatitis B. Sustained loss of HBV DNA alone as a result of cccDNA elimination is also a potentially approvable endpoint for the FDA and highly relevant for PBGENE-HBV.

About PBGENE-HBV, A 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 be a potentially curative treatment for chronic hepatitis B infection. PBGENE-HBV is the first and only potentially curative gene editing program to enter the clinic that is specifically designed to eliminate the root cause of chronic hepatitis B, cccDNA, while inactivating integrated HBV DNA. Elimination of cccDNA results in HBV cure as cccDNA is the only source of infectious replication (HBV DNA). The ELIMINATE-B trial is investigating PBGENE-HBV at multiple dose levels across a number of administrations per dose level in patients with chronic hepatitis B. PBGENE-HBV has been granted Fast Track designation by the FDA.

PBGENE-HBV is the only clinical stage program targeting the elimination of cccDNA leading to sustained loss of HBV DNA. The FDA has previously provided guidance that sustained loss of HBV DNA is an approvable endpoint for chronic hepatitis B.

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

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; the expectation that the addition of sites in France and Romania support broader patient enrollment in ELIMINATE-B and continued clinical execution; the goal to treat as many clinical trial patients as possible with PBGENE-HBV following the addition of sites in France and Romania; the strong investigator interest in PBGENE-HBV; the belief that since cccDNA is the only source of infectious particles (HBV DNA), elimination of cccDNA could result in a cure of chronic hepatitis B; the belief that PBGENE-HBV is the only clinical stage program targeting the elimination of cccDNA leading to sustained loss of HBV DNA; the potential that sustained loss of HBV DNA alone as a result of cccDNA elimination is an approvable endpoint for the FDA and highly relevant for PBGENE-HBV; the design of PBGENE-HBV to be a potentially curative treatment for chronic hepatitis B infection; the expectation that site initiation activities are underway in France and Romania, with initial patient screening expected in Q2 2026; and the design of

PBGENE-HBV to be the first and only potentially curative gene editing program to enter the clinic that is specifically designed to eliminate the root cause of chronic hepatitis B. 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-K for the annual period ended December 31, 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.

View source version on businesswire.com: https://www.businesswire.com/news/home/20260415450685/en/

Investor and Media Contact:
Naresh Tanna
Vice President of Investor Relations
naresh.tanna@precisionbiosciences.com

Source: Precision BioSciences, Inc.