



Precision BioSciences Presents Late-Breaking Data Highlighting Preclinical Efficacy and Safety of PBGENE-HBV for Chronic Hepatitis B at AASLD's The Liver Meeting 2023

November 13, 2023 at 7:05 AM EST

- PBGENE-HBV designed to both eliminate cccDNA and inactivate HBV DNA
- Data demonstrates strong proof of concept efficacy including up to 99% viral engagement and no detectable off-target editing at maximal on-target editing dose
- PBGENE-HBV final clinical candidate ready with CTA and/or IND filing targeted in 2024
- Company to host webcast at 4:30 pm ET on Monday, November 13, 2023

DURHAM, N.C.--(BUSINESS WIRE)--Nov. 13, 2023-- Precision BioSciences, Inc. (Nasdaq: DTIL), an advanced gene editing company utilizing its novel proprietary ARCUS[®] platform to develop *in vivo* gene editing therapies for sophisticated gene edits, including gene insertion, excision, and elimination, announced that the company will present late-breaking data today at the American Association for the Study of Liver Diseases' (AASLD) The Liver Meeting being held in Boston, MA. The poster highlights preclinical data demonstrating PBGENE-HBV's ability to eliminate cccDNA and inactivate hepatitis B virus (HBV) DNA, meriting further investigation as a potentially curative treatment for chronic hepatitis B (CHB).

The late-breaking poster, titled "*Preclinical efficacy and safety of ARCUS-POL nucleases for chronic hepatitis B: a potentially curative strategy*", will be on display on Monday, November 13 from 1:00 PM – 2:00 PM ET in Hall C.

Based on data to be presented today in a non-human primate model of HBV, the ARCUS nuclease was well tolerated and demonstrated up to 99% viral engagement which is defined as the percent of viral DNA that is either eliminated or inactivated following treatment. The final clinical candidate nuclease demonstrated no detectable off-target editing at doses that maximized on-target editing. In multiple HBV disease models, PBGENE-HBV demonstrated ability to inhibit viral markers and eliminate cccDNA in HBV-infected primary human liver cells. These data are further supported by a high level of viral engagement and a 95% reduction in hepatitis B surface antigen (HBsAg) in an episomal HBV mouse model. Finally, the company shared data from a transgenic mouse model of HBV that demonstrated PBGENE-HBV resulted in sustained reduction of HBV DNA even after stopping nucleos(t)ide analog treatment.

"Eliminating cccDNA and inactivating integrated HBV DNA are both essential to drive a durable loss of viral markers and achieve a functional cure for HBV," said Jeff Smith, Ph.D., Co-Founder and Chief Research Officer of Precision BioSciences. "In the data presented today, we have demonstrated the ability of our PBGENE-HBV program to durably achieve a near-complete reduction across these viral markers including HBsAg, hepatitis B e-antigen (HBeAg), HBV DNA and HBV RNA. We believe that these data further validate our HBV program and enable us to progress the final clinical candidate toward anticipated clinical trial application (CTA) and/or investigational new drug (IND) application in 2024."

Company-Hosted Webcast and Conference Call Information:

Precision will host a conference call and webcast on Monday, November 13, 2023 at 4:30 PM ET to discuss PBGENE-HBV program updates. The dial-in conference call number is (800) 715-9871 and the conference ID number for the call is 3866428. Participants may access the live webcast, and accompanying presentation materials, as well as the archived webcast on Precision's website in the Investors section under Events & Presentations: <https://investor.precisionbiosciences.com/events-and-presentations>.

About Hepatitis B and the PBGENE-HBV development candidate:

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 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. PBGENE-HBV is a highly specific, novel therapeutic approach to treating patients with chronic HBV infection. It's designed to directly eliminate cccDNA and inactivate integrated HBV DNA with high specificity, resulting in degraded cccDNA and a reduction in HBsAg.

About ARCUS

ARCUS is a proprietary genome editing technology discovered and developed by scientists at Precision BioSciences. It uses sequence-specific DNA-cutting enzymes, or nucleases, that are designed to either insert, excise, or eliminate DNA of living cells and organisms. ARCUS is based on a naturally occurring genome editing enzyme, I-CreI, that evolved in the algae *Chlamydomonas reinhardtii* to make highly specific cuts in cellular DNA and stimulate gene insertion at the cut site by homologous recombination. Precision's platform and products are protected by a comprehensive

portfolio including nearly 100 patents to date.

About Precision BioSciences, Inc.

Precision BioSciences, Inc. is an advanced 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.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. The Company intends such forward-looking statements to be covered by the safe harbor provisions for forward-looking statements contained in Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. 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 and gene editing approaches including ARCUS's potential editing efficiency and differentiating aspects and the ability for the ARCUS genome editing platform to develop differentiated programs; the suitability of ARCUS nucleases for gene or viral elimination, large excision, gene insertion, and other complex gene editing approaches to drive defined outcomes; the potential of PBGENE-HBV to durably achieve a near-complete reduction across viral markers including HBsAg, HBeAg, HBV DNA and HBV RNA and as a potentially curative treatment for CHB with no off-target editing at maximal on-target editing dose; and the expected timing of regulatory processes, including timing of expected CTA and/or IND filings. The words "aim," "anticipate," "approach," "believe," "contemplate," "could," "designed," "estimate," "expect," "goal," "intend," "look," "may," "mission," "plan," "possible," "potential," "predict," "project," "promise," "pursue," "should," "target," "will," "would," and other similar words or expressions, or the negative of these words or similar words or expressions, are intended to identify forward-looking statements, though not all forward-looking statements use these words or 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, but involve 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 raising additional capital and requirements under our current debt instruments and effects of restrictions thereunder; our operating expenses and our ability to predict what those expenses will be; our limited operating history; the 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; our dependence on our ARCUS technology; the risk that other genome-editing technologies may provide significant advantages over our ARCUS technology; the initiation, cost, timing, progress, achievement of milestones and results of research and development activities, preclinical studies and clinical trials; public perception about genome editing technology and its applications; competition in the genome editing, biopharmaceutical, and biotechnology fields; our or our collaborators' ability to identify, develop and commercialize product candidates; potential product liability lawsuits and penalties against us or our collaborators related to our technology and our product candidates; the U.S. and foreign regulatory landscape applicable to our and our collaborators' development of product candidates; our or our collaborators' or other licensees' ability to advance product candidates into, and successfully design, implement and complete, clinical or field trials; our or our collaborators' other licensees' ability to advance product candidates into, and successfully design, implement and complete, clinical or field trials; potential manufacturing problems associated with the development or commercialization of any of our product candidates; delays or difficulties in our and our collaborators' 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; the rate and degree of market acceptance of any of our product candidates; the success of our existing collaboration 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; our ability to effectively manage the growth of our operations; our ability to attract, retain, and motivate key executives and personnel; market and economic conditions; effects of system failures and security breaches; 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; insurance expenses and exposure to uninsured liabilities; effects of tax rules; risks related to ownership of our common stock; 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, 2023, 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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Source: Precision BioSciences, Inc.