



Assembly Biosciences Doses First Two Participants in Phase 2 Study of Oral NTCP Inhibitor ABI-6250 for Chronic Hepatitis Delta Virus

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- Phase 2 study will evaluate the safety, pharmacokinetics and antiviral activity of ABI-6250 in participants with chronic HDV infection –*
- Initial data from the Phase 2 study is expected in the fourth quarter of 2027 –*

SOUTH SAN FRANCISCO, Calif., Oct. 29, 2026 (GLOBE NEWSWIRE) -- Assembly Biosciences, Inc. (Nasdaq: ASMB), a biotechnology company developing innovative therapeutics targeting serious viral and liver diseases, today announced dosing of the first two participants in a Phase 2 clinical study of ABI-6250, the company's investigational oral small-molecule entry inhibitor candidate, in participants with chronic hepatitis delta virus (HDV) infection.

The Phase 2 study is expected to enroll approximately 80 participants with chronic HDV infection and will evaluate two once-daily oral dose levels of ABI-6250. The study will evaluate safety, pharmacokinetics, pharmacodynamics and efficacy, including changes from baseline in HDV RNA and alanine aminotransferase levels. Initial data from the study is expected in the fourth quarter of 2027.

Chronic HDV infection is the most severe form of viral hepatitis and results in more rapid progression to cirrhosis, liver cancer, decompensated liver disease or death than other forms of hepatitis. Treatment options remain limited, with only one approved therapy, a peptide inhibitor of sodium taurocholate cotransporting polypeptide (NTCP) that requires daily injections, underscoring the need for effective oral treatment options.

"Advancing ABI-6250 into Phase 2 represents an important milestone in our efforts to provide people living with chronic HDV infection a convenient, once-daily oral alternative to the currently available daily injectable therapy," said Anuj Gaggar, MD, PhD, chief medical officer of Assembly Bio. "Supported by encouraging Phase 1a findings, this study will help evaluate the potential of ABI-6250 to deliver meaningful antiviral activity through a differentiated treatment approach."

In the completed Phase 1a study in healthy participants, ABI-6250 demonstrated a safety and pharmacokinetic profile supporting advancement into Phase 2 development. ABI-6250 had a mean half-life of approximately four days, supporting once-daily oral dosing, and changes in serum bile acids were consistent with NTCP target engagement. The Phase 1a findings were supported by preclinical data demonstrating low nanomolar potency across multiple HDV genotypes in vitro and selectivity for NTCP versus other bile acid transporters.

Under Assembly Bio's collaboration agreement with Gilead Sciences, Inc. (Gilead), Gilead has the right to obtain an exclusive license for further development and commercialization of ABI-6250 through completion of the Phase 2 study and delivery and review of the related option data package for a \$90 million opt-in fee.

About the ABI-6250 Phase 2 Study

ABI-6250-201 is a multicenter, open-label Phase 2 clinical study expected to enroll approximately 80 participants with chronic HDV infection. In the main cohort, approximately 50 participants will receive a low or high dose of once-daily oral ABI-6250 or enter a delayed-treatment group. Following analysis of the main cohort's Week 16 primary endpoint, a dose will be selected for an expansion cohort of approximately 20 to 30 additional participants. The expansion cohort is designed to provide additional safety data to support potential Phase 3 development.

The study will evaluate safety, pharmacokinetics, pharmacodynamics and antiviral activity, with key efficacy measures including changes from baseline in HDV RNA and alanine aminotransferase levels.

Additional information about the Phase 2 study is available at clinicaltrials.gov using the identifier NCT07762027.

About ABI-6250

ABI-6250 is an investigational first-in-class oral small-molecule inhibitor of the sodium taurocholate co-transporting polypeptide (NTCP), a membrane protein selectively expressed on hepatocytes that facilitates bile acid transport into hepatocytes and also serves as the receptor for hepatitis B virus (HBV) and hepatitis delta virus (HDV) to enter hepatocytes. Assembly Bio is developing ABI-6250 for the treatment of chronic HDV infection, where inhibition of NTCP blocks viral entry and represents a clinically validated therapeutic mechanism. ABI-6250 is also being evaluated in cholestatic liver diseases, such as primary biliary cholangitis

(PBC) and primary sclerosing cholangitis (PSC), where bile acid accumulation in the liver drives liver inflammation and liver injury.

About the Assembly Bio-Gilead Collaboration

In October 2023, Assembly Bio and Gilead entered into a 12-year collaboration to advance the research and development of novel antiviral therapies. Under the collaboration, Gilead has an option to obtain exclusive rights to each of Assembly Bio's current and future programs, and Assembly Bio is eligible to receive collaboration extension fees, option fees, milestone payments and royalties. Following Gilead's exercise of an option, Assembly Bio has the right to elect to share profits and costs in the U.S., as well as certain co-promotion rights for future programs.

To date, Gilead has exercised its option for Assembly Bio's helicase-primase inhibitor program for recurrent genital herpes, and Assembly Bio has elected to participate in a 40% U.S. cost and profit share for the program.

About Assembly Biosciences

Assembly Biosciences is a biotechnology company developing innovative small-molecule therapeutics aimed at advancing the treatment paradigm of serious viral and liver diseases and improving the lives of patients worldwide. Led by an accomplished leadership team in antiviral and liver disease drug development, Assembly Bio is committed to improving outcomes for people living with the chronic impacts of herpesviruses, hepatitis delta virus (HDV) infections, cholestatic liver diseases and hepatitis B virus (HBV). For more information, visit assemblybio.com.

Forward-Looking Statements

The information in this press release contains forward-looking statements that are subject to certain risks and uncertainties that could cause actual results to materially differ. These risks and uncertainties include: Assembly Bio's ability to realize the potential benefits of its collaboration with Gilead, including all financial aspects of the collaboration and equity investments; Assembly Bio's ability to initiate and complete clinical studies involving its therapeutic product candidates, including studies contemplated by Assembly Bio's collaboration with Gilead, including studies conducted by Gilead, in the currently anticipated timeframes or at all; safety and efficacy data from clinical or nonclinical studies may not warrant further development of product candidates; clinical and nonclinical data may not differentiate product candidates from other companies' candidates; Assembly Bio's ability to maintain financial resources and secure additional funding necessary to continue its research activities, clinical studies, and other business operations; potential effects of changes in government regulation; results of nonclinical studies may not be representative of disease behavior in a clinical setting and may not be predictive of the outcomes of clinical studies; and other risks identified from time to time in Assembly Bio's reports filed with the U.S. Securities and Exchange Commission (the SEC). You are urged to consider statements that include the words may, will, would, could, should, might, believes, hopes, estimates, projects, potential, expects, plans, anticipates, intends, continues, forecast, designed, goal or the negative of those words or other comparable words to be uncertain and forward-looking. Assembly Bio intends such forward-looking statements to be covered by the safe harbor provisions contained in Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. More information about Assembly Bio's risks and uncertainties are more fully detailed under the heading "Risk Factors" in Assembly Bio's filings with the SEC, including its most recent Annual Report on Form 10-K, Quarterly Reports on Form 10-Q and Current Reports on Form 8-K. Except as required by law, Assembly Bio assumes no obligation to update publicly any forward-looking statements, whether as a result of new information, future events or otherwise.

Contacts:

Investors:

Patrick Till

Meru Advisors

(484) 788-8560

investor_relations@assemblybio.com

Media:

Mike Beyer

Sam Brown LLC

(312) 961-2502

ASMBMedia@sambrown.com