New Preclinical Data for Assembly Biosciences' Oral Hepatitis D Virus Entry Inhibitor ABI-6250 and Next-Generation Hepatitis B Virus Capsid Assembly Modulator ABI-4334 Presented at the EASL Congress 2025

May 7, 2025

– Late-breaker poster highlights preclinical profile of ABI-6250, currently in Phase 1a with data anticipated in Q3 2025 –

– Second poster describes in vitro studies of effects on viral infection markers by ABI-4334, currently in Phase 1b with data anticipated in the first half of 2025 –

SOUTH SAN FRANCISCO, Calif., May 07, 2025 (GLOBE NEWSWIRE) -- Assembly Biosciences, Inc. (Nasdaq: ASMB), a biotechnology company developing innovative therapeutics targeting serious viral diseases, today announced new preclinical and *in vitro* data for two therapeutic candidates featured in poster presentations, including one late-breaker, at the European Association for the Study of the Liver (EASL) Congress, taking place May 7-10, 2025, in Amsterdam, the Netherlands.

"These two EASL poster presentations provide additional characterization of our therapeutic candidates in clinical development for viral hepatitis," said Anuj Gaggar, MD, PhD, chief medical officer of Assembly Bio. "Our late-breaker poster highlights ABI-6250's preclinical profile and potential as a once-daily oral therapy for chronic HDV infection, a severe form of viral hepatitis with limited treatment options available. Additionally, *in vitro* data presented for ABI-4334 provide further insights into the potential for next-generation capsid assembly modulators to impact markers of chronic HBV infection. We look forward to sharing data from ongoing clinical studies for both candidates later this year."

ABI-6250: An oral viral entry inhibitor candidate for hepatitis D virus (HDV) infection

The late-breaker poster presentation titled "*Preclinical profiling of ABI-6250, a first-in-class oral therapeutic candidate for chronic hepatitis D*" highlights preclinical data supporting the advancement of ABI-6250 into an ongoing Phase 1a clinical study.

Results demonstrate that in cell culture, ABI-6250 specifically inhibits both HDV and hepatitis B virus (HBV) at low nanomolar levels and shows selectivity versus a panel of other viruses. ABI-6250 showed minimal effects on cell viability *in vitro* across multiple cell types, and also selectively inhibited the sodium taurocholate cotransporting polypeptide (NTCP) bile acid transporter compared to a broad range of other transporters *in vitro. In vivo*, treatment with ABI-6250 elevated total bile acids at doses that did not increase biomarkers for inhibition of other transporters, indicating selective NTCP target engagement. These results support ABI-6250 as an inhibitor of NTCP and describe total bile acids as a biomarker for target engagement that Assembly Bio plans to evaluate in the ongoing Phase 1a study.

Chronic HDV infection (cHDV) is considered the most serious form of viral hepatitis, and can result in liver cirrhosis, liver cancer, decompensated liver disease or death. ABI-6250 acts to prevent the entry of HDV into cells by blocking access to the NTCP bile acid transporter, a clinically validated target for HDV infection. Currently, one therapy, a peptide inhibitor of NTCP requiring daily injections, is approved for cHDV in the European Union with no therapies approved in the United States.

ABI-4334: A next-generation highly potent capsid assembly modulator (CAM) for HBV

The poster presentation titled "*Sustained inhibition of HBV replication and HBsAg levels after long-term treatment with CAM ABI-4334 in human hepatocytes*" describes *in vitro* studies of ABI-4334 evaluating multiple viral biomarkers of HBV infection. These results showed durable reduction in HBV nucleic acids and antigens in human hepatocytes following a one-month course of treatment with ABI-4334.

HBV is a leading global cause of chronic liver disease and liver transplants. The WHO estimates 254 million people worldwide are chronically infected with HBV with an estimated 1.1 million deaths in 2022. The current standard of care for chronic HBV (cHBV) infection, nucleos(t)ide analog reverse transcriptase inhibitors (NrtIs), require lifelong administration and reduce, but do not eliminate, the virus and result in very low cure rates. No new mechanisms of action have been approved for the treatment of cHBV infection in over 25 years.

Assembly Bio intends to make the posters available on the "Events & Presentations" page in the "Investors" section and on the "Publications" page in the "Pipeline" section of its website at www.assemblybio.com.

ABI-6250 and ABI-4334 are investigational product candidates that have not been approved anywhere globally, and their safety

and efficacy have not been established.

About Assembly Biosciences
Assembly Biosciences is a biotechnology company dedicated to the development of innovative small-molecule therapeutics designed to change the path of serious viral diseases and improve the lives of patients worldwide. Led by an accomplished team of leaders in virologic drug development, Assembly Bio is committed to improving outcomes for patients struggling with the serious, chronic impacts of herpesvirus, hepatitis B virus (HBV) and hepatitis delta virus (HDV) infections. 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 maintain financial resources necessary to continue its research activities, clinical studies and other business operations; Assembly Bio's ability to realize the potential benefits of its collaboration with Gilead Sciences, Inc., 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, in the currently anticipated timeframes or at all; safety and efficacy data from clinical or nonclinical studies may not warrant further development of Assembly Bio's product candidates; clinical and nonclinical data may not differentiate Assembly Bio's product candidates from other companies' candidates; potential effects of changes in government regulation, including as a result of the change in U.S. administration in 2025; 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.

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