Assembly Biosciences Doses First Participant in Phase 1a Clinical Study of Oral Entry Inhibitor Candidate ABI-6250 for Hepatitis Delta Virus

February 26, 2025

– Phase 1a study will evaluate single and multiple ascending doses of ABI-6250 in healthy participants with data expected in Q3 2025 –

– Biomarker of ABI-6250 target engagement, serum bile acids, will be assessed in addition to safety and pharmacokinetic measures –

SOUTH SAN FRANCISCO, Calif., Feb. 26, 2025 (GLOBE NEWSWIRE) -- Assembly Biosciences, Inc. (Nasdaq: ASMB), a biotechnology company developing innovative therapeutics targeting serious viral diseases, today announced that the first participant has been dosed in the Phase 1a trial of ABI-6250, the company's orally bioavailable, small molecule hepatitis delta virus (HDV) entry inhibitor candidate.

This Phase 1a study will evaluate the safety, tolerability and pharmacokinetics (PK) of ABI-6250 across single and multiple ascending dose cohorts in healthy participants. In addition, the study will look at serum bile acids as a biomarker of ABI-6250's engagement of its target, the transporter used by HDV to infect hepatocytes (sodium taurocholate cotransporting polypeptide or NTCP). Assembly Bio expects to share data from the Phase 1a study in Q3 2025.

Currently, one therapy is approved for chronic HDV infection (cHDV) in the European Union with no therapies approved in the United States. This approved therapy is a peptide inhibitor of NTCP requiring daily injections. Well-tolerated serum bile acid elevations have been observed clinically with the approved NTCP inhibitor.

"ABI-6250 has the potential to be the first oral therapy for cHDV, a life-threatening chronic viral infection with limited treatment options available," said Anuj Gaggar, MD, PhD, chief medical officer of Assembly Bio. "Chronic HDV is the most severe form of viral hepatitis with 70% of individuals with cHDV progressing to cirrhosis within 10 years, and we are excited to have clinical studies underway for this candidate with the potential to simplify cHDV treatment."

In preclinical studies, ABI-6250 has demonstrated low nanomolar potency across multiple HDV genotypes *in vitro,* selectivity for NTCP versus other bile acid transporters and a PK profile supportive of once-daily oral dosing.

ABI-6250 is an investigational product candidate that has not been approved anywhere globally, and its safety and efficacy have not been established.

About ABI-6250-101

ABI-6250-101 is a randomized, blinded and placebo-controlled Phase 1a clinical study evaluating the safety, tolerability and PK of ABI-6250 following single and multiple ascending dose administration. Healthy participants will be randomized between ABI-6250 and placebo in up to five single-dose and five multiple-dose cohorts at different doses. Multiple-dose cohorts will evaluate repeat dosing over 10 days.

In addition to assessing safety, tolerability and PK, this Phase 1a study will also measure changes in serum bile acid levels, a biomarker of NTCP engagement. The trial results will support dose selection for future clinical studies.

Additional information about the Phase 1a trial is available at clinicaltrials.gov using the identifier NCT06740474.

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 presented at conferences may not differentiate Assembly Bio's product candidates from other companies' candidates; 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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