Assembly Biosciences Presents Positive Phase 1b Data for Next-Generation Capsid Assembly Modulator ABI-4334 at AASLD The Liver Meeting®

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– Phase 1b data demonstrating favorable safety and tolerability profile and potent reductions in viral nucleic acids highlighted in late-breaking poster presentation –

SOUTH SAN FRANCISCO, Calif., Nov. 07, 2025 (GLOBE NEWSWIRE) -- Assembly Biosciences, Inc. (Nasdaq: ASMB), a biotechnology company developing innovative therapeutics targeting serious viral diseases, today announced Phase 1b clinical data for its next-generation investigational capsid assembly modulator (CAM) ABI-4334 featured in a late-breaking poster presentation at the American Association for the Study of Liver Diseases (AASLD), The Liver Meeting®. The conference is taking place November 7-11, 2025, in Washington, D.C.

"We are pleased to highlight positive data from our Phase 1b study for ABI-4334 with the scientific community," said Anuj Gaggar, MD, PhD, chief medical officer of Assembly Bio. "These data demonstrate the very high potency we set out to achieve for ABI-4334 and support its potential to maximize antiviral activity as a component of multi-drug combination regimens targeting cures for chronic hepatitis B infection."

The late-breaking poster presentation titled "Safety, pharmacokinetics and antiviral activity of the next-generation hepatitis B capsid assembly modulator ABI-4334 in patients with HBeAg-negative chronic hepatitis B infection not suppressed on nucleoside analogues: results from a randomized, blinded, Phase 1b study" highlights data in individuals with chronic hepatitis B infection treated with ABI-4334. This poster is the first scientific presentation of the complete Phase 1b data announced earlier this year by Assembly Bio.

Two cohorts of predominantly HBeAg-negative subjects were enrolled, evaluating 150 mg and 400 mg oral doses of ABI-4334 given once-daily over 28 days. ABI-4334 was well tolerated at both doses evaluated. Multi-log declines in hepatitis B virus (HBV) DNA and pregenomic RNA (pgRNA) were observed for both doses, consistent with the increased *in vitro* potency of ABI-4334 compared to first-generation CAMs. These declines in HBV DNA and pgRNA are supportive of full engagement of the first CAM mechanism of action, suppression of viral replication. Exposures multiple folds above levels anticipated to be required for inhibition of cccDNA formation, the second CAM mechanism of action, were also observed at both dose levels. As expected in predominantly HBeAg-negative patients with a short dosing interval, reductions in HBsAg were not observed.

The poster presentation is available on the "Events & Presentations" page in the "Investors" section and on the "Publications" page in the "Pipeline" section of Assembly Bio's website at www.assemblybio.com.

Under the collaboration agreement between Assembly Bio and Gilead Sciences, Inc. (Gilead), Gilead has the right to opt in to an exclusive license for further development and commercialization of ABI-4334 after reviewing an option data package following completion of this Phase 1b study.

ABI-4334 is an investigational product candidate that has not been approved anywhere globally, and its 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 and secure additional funding 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, 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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