Assembly Biosciences Doses First Participant in Phase 1b Clinical Trial Evaluating Next-Generation Capsid Assembly Modulator Candidate ABI-4334 for the Treatment of Chronic Hepatitis B Virus Infection

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– Phase 1b study will evaluate safety, pharmacokinetic and efficacy endpoints in participants with chronic hepatitis B virus infection with interim data expected by the end of 2024 –

SOUTH SAN FRANCISCO, Calif., June 18, 2024 (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 1b trial of ABI-4334, a next-generation capsid assembly modulator (CAM) candidate in development for the treatment of chronic hepatitis B virus (HBV) infection.

Chronic HBV (cHBV) infection is a leading cause of chronic liver disease and liver transplants globally, with the World Health Organization estimating that over one million people died in 2022 from HBV-related causes. Current treatments are lifelong and reduce, but do not eliminate, the virus with very low cure rates. CAMs are direct-acting antivirals with two distinct mechanisms of action, inhibition of HBV DNA replication and prevention of the formation of new cccDNA, the viral reservoir. ABI-4334 is a highly potent next-generation CAM with a potential best-in-class profile and has been specifically optimized to target both mechanisms.

In a Phase 1a study, once-daily oral dosing with ABI-4334 demonstrated a favorable safety and pharmacokinetic (PK) profile in healthy participants, with ABI-4334 exposure levels projected to achieve strong antiviral activity and double-digit multiples over protein adjusted EC_{50} for both HBV DNA replication and cccDNA formation. *In vitro,* ABI-4334 has shown single-digit nanomolar potency against both mechanisms of action and the ability to impact HBV DNA integration. The Phase 1b study that is currently enrolling will evaluate safety, PK and antiviral activity in individuals with cHBV infection over a 28-day treatment period.

“We believe ABI-4334 has the potential to demonstrate best-in-class antiviral activity in line with the very high potency seen preclinically and are pleased to initiate dosing for this differentiated investigational therapy in individuals with cHBV,” said Anuj Gaggar, MD, PhD, chief medical officer of Assembly Bio. “In this 28-day placebo-controlled study, we will be able to measure the impact of escalating doses of ABI-4334 on HBV DNA and refine the projected activity against cccDNA formation, along with generating key safety data. We look forward to reporting interim results from the study later this year.”

About ABI-4334-102

ABI-4334-102 is a randomized, blinded and placebo-controlled dose-ranging Phase 1b study that will evaluate the safety, PK and antiviral activity of ABI-4334 in participants with cHBV infection.

Participants may be treatment-naïve or off-treatment and hepatitis B e antigen (HBeAg) positive or negative. The dose-escalation trial will enroll up to five sequential cohorts of 10 subjects each, for a total of up to 50 subjects, randomized 8:2 between ABI-4334 and placebo with a treatment period of 28 days.

The objectives of the study include assessments of safety, tolerability and PK for ABI-4334, as well as changes in HBV DNA associated with ABI-4334 treatment. The results of the trial will support dose selection for future clinical trials.

Additional information about the trial is available at clinicaltrials.gov using the identifier NCT06384131. 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 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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