Assembly Biosciences Doses First Subject in Phase 1a Clinical Trial to Evaluate Safety, Tolerability and Pharmacokinetic Profile of Investigational Next Generation Core Inhibitor ABI-4334

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Healthy volunteer study will inform development of 4334 for treatment of hepatitis B virus

SOUTH SAN FRANCISCO, Calif., Nov. 14, 2022 (GLOBE NEWSWIRE) -- Assembly Biosciences, Inc. (Nasdaq: ASMB), a clinical-stage biotechnology company developing innovative, investigational therapeutics targeting hepatitis B virus (HBV) and other viral diseases, today announced that the first subject has been dosed in the Phase 1a trial of its investigational core inhibitor ABI-4334 (4334).

4334 is an investigational next-generation core inhibitor that is optimized for significantly increased potency against covalently closed circular DNA (cccDNA) formation and new virus production versus first-generation core inhibitors. In preclinical research, 4334 has demonstrated sub-nanomolar potency against pgRNA encapsidation and 2-3 nanomolar potency against cccDNA formation. Chronic HBV infection is a debilitating disease of the liver that is estimated to impact approximately 296 million people worldwide. HBV is the leading cause of chronic liver disease and need for liver transplantation, and up to one million people worldwide die every year from HBV-related causes.

“The initiation of this first-in-human clinical trial for our investigational next-generation core inhibitor 4334, our most potent core inhibitor, marks a significant milestone in advancing toward our goal of delivering novel finite and curative therapies for HBV that target multiple steps during viral replication to suppress the production of new virus, particularly the formation of new cccDNA, the viral reservoir,” said Michele Anderson, chief development officer of Assembly Bio. “Most importantly, this trial underscores our commitment to addressing critical unmet needs for patients with HBV as we pursue our mission of making a profound impact on patients’ lives.”

The Phase 1a clinical trial is a randomized, blinded and placebo-controlled study that will evaluate the safety, tolerability and pharmacokinetics of 4334 following single ascending dose and multiple ascending dose administration in healthy participants. The objectives of the study include the proportion of subjects with adverse events (AEs), premature treatment discontinuation due to AEs and abnormal laboratory results. Results of the trial will support dose selection for a future Phase 2 trial.

Additional information about the trial is available at clinicaltrials.gov using the identifier NCT05569941. Data from the preclinical research program that supported clinical advancement for 4334 was recently presented at The Liver Meeting® hosted by the American Association for the Study of Liver Diseases (AASLD) in a poster available on Assembly Bio’s website at: https://investor.assemblybio.com/events/event-details/liver-meeting-2022.

About Assembly Biosciences
Assembly Bio is a clinical-stage biotechnology company pioneering the development of novel therapeutics for serious viral diseases. Assembly Bio is advancing a leading portfolio of more potent, next-generation core inhibitor drug candidates that aim to break the complex viral replication cycle of hepatitis B virus (HBV) to achieve finite and potentially curative therapies for the 296 million people living with HBV worldwide. The company’s research pipeline includes differentiated antiviral approaches against HBV/hepatitis delta virus and herpesviruses. 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 successfully execute its previously announced reprioritization and restructuring activities, including the CEO transition; potential adverse legal, reputational, operational and financial effects on Assembly Bio resulting from the reprioritization and restructuring activities; Assembly Bio’s ability to initiate and complete clinical studies involving its therapeutic product candidates, including studies contemplated by Assembly Bio’s collaboration agreements, in the currently anticipated timeframes; safety and efficacy data from clinical 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; continued development and commercialization of ABI-H3733, if successful, in the China territory will be dependent on, and subject to, Assembly Bio’s collaboration agreement governing this activity in the China territory; Assembly Bio’s ability to maintain financial resources necessary to continue its clinical studies and fund business operations; any impact that the COVID-19 pandemic may have on Assembly Bio’s business and operations, including initiation, enrollment and continuation of its clinical

studies or timing of discussions with regulatory authorities; 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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