Assembly Biosciences Initiates Phase 1b Clinical Trial Evaluating Next Generation Core Inhibitor ABI-H3733 for the Treatment of Chronic Hepatitis B Virus Infection

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SOUTH SAN FRANCISCO, Calif., June 06, 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 the initiation of a Phase 1b trial of its investigational next-generation, highly potent core inhibitor ABI-H3733 (3733).

3733 has demonstrated significantly increased potency against covalently closed circular DNA (cccDNA) formation and new virus production as compared to first-generation core inhibitors in preclinical studies, consistent with the company's strategy to optimize its next-generation candidates for antiviral activity against both mechanisms. This trial builds upon the results of a previous Phase 1a study of 3733 showing a favorable safety and pharmacokinetic profile and will evaluate a new tablet formulation with the potential for convenient once-daily dosing.

"We look forward to better understanding the safety profile and impact of activity of this novel, next-generation core inhibitor candidate in patients with chronic HBV infection through this trial," said John McHutchison, AO, MD, chief executive officer and president of Assembly Bio. "This study initiation serves as an important milestone in the clinical development program for 3733, a promising candidate that has demonstrated increased potency against both HBV core inhibitor mechanisms and against cccDNA formation in particular, and advances our strategy to pursue finite and curative HBV therapies."

The Phase 1b clinical trial is a randomized, multi-center, double-blind and placebo-controlled study that will evaluate the safety, pharmacokinetics and antiviral activity of 3733 in adults with chronic HBV (cHBV) infection. The dose-escalation trial will enroll approximately 50 patients with diagnosed cHBV infection who are treatment naïve or who are off treatment. Patients will be randomized 8:2 between the new tablet formulation of 3733 and placebo for a period of 28 days. The objectives of the study include assessments of safety, tolerability and pharmacokinetics of 3733 in patients with cHBV infection, as well as changes in HBV DNA and other viral parameters associated with 3733 treatment. Results of the trial will support dose selection for a future Phase 2 trial.

Additional information about the Phase 1b clinical trial will be available at www.clinicaltrials.gov. Additional details about the new tablet formulation of 3733 will be provided in a poster accepted for presentation at the International Liver Congress™ (ILC), the Annual Meeting of the European Association for the Study of the Liver (EASL), taking place virtually and in person in London on June 22-26, 2022.

About Assembly Biosciences
Assembly Bio is a clinical-stage biotechnology company committed to bringing finite and curative therapies to the 296 million people living with hepatitis B virus (HBV) worldwide. A pioneer in the development of a new class of potent, oral investigational core inhibitors, Assembly Bio's approach aims to break the complex viral replication cycle of HBV to free patients from a lifetime of therapy. Assembly Bio's strategy includes a leading portfolio of more potent, next-generation core inhibitor drug candidates, proof-of-concept combination studies for HBV cure and research programs focused on the discovery of additional novel antiviral mechanisms for HBV and other viral diseases. 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 initiate and complete clinical studies involving its therapeutic product candidates, including studies contemplated by Assembly Bio's clinical 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 Assembly Bio's HBV product candidates, if successful, in the China territory will be dependent on, and subject to, Assembly Bio's collaboration agreement governing its HBV-related 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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