Assembly Biosciences Announces Additional Promising Data from Phase 1a Clinical Trial Evaluating Highly Potent Next-Generation Core Inhibitor Candidate ABI-4334 and Provides Pipeline Update

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- *Phase 1a clinical data for remaining 200 mg multiple dose cohort for ABI-4334 continue to demonstrate encouraging clinical profile with strong projected activity against both viral replication and cccDNA formation*
- *Assembly Bio will evaluate partnering options for its core inhibitor portfolio prior to further clinical development of the mechanism for HBV cure*
- *The company will prioritize resources on its promising portfolio of antiviral programs with a faster path to clinical proof of concept, including ABI-5366 for high-recurrence genital herpes*

SOUTH SAN FRANCISCO, Calif., April 18, 2023 (GLOBE NEWSWIRE) -- Assembly Biosciences, Inc. (Nasdaq: ASMB), a biotechnology company developing innovative antiviral therapeutics targeting serious viral diseases, today provided an update of results from the final multiple-dose cohort in the ongoing Phase 1a study of its investigational next-generation, highly potent hepatitis B virus (HBV) core inhibitor, ABI-4334 (4334), and announced it will evaluate partnering opportunities for its core inhibitor portfolio and prioritize its expanded virology pipeline.

“We are encouraged by the promising clinical profile of our most potent core inhibitor candidate, 4334, and its potential to reach the clinical exposures needed for both potent antiviral activity and inhibition of cccDNA formation,” said Jason Okazaki, chief executive officer and president of Assembly Bio. “While we are enthusiastic about these results and the antiviral activity shown in our Phase 1b study of our other next-generation core inhibitor, 3733, in HBV patients, we recognize that demonstrating the ability of next-generation core inhibitors to inhibit cccDNA formation in the clinic, which we view as a critical part of HBV cure, will require longer-duration Phase 2 studies. Because of this, we believe partnering our core inhibitor portfolio would enable additional opportunities for further clinical development for this compelling mechanism aimed at achieving a functional cure for HBV, including opening up other avenues for combination approaches.”

“We are prioritizing our expanded virology pipeline because we believe these programs offer higher potential to have a near-term impact for patients and stockholders,” continued Mr. Okazaki. “Over the past three years, we have built a strategically diverse portfolio designed to address significant unmet medical needs with shorter timelines to key inflection points and clinical proof of concept than our core inhibitor portfolio. To that end, we anticipate entering the clinic with the first of these program candidates, the long-acting helicase inhibitor ABI-5366 for treatment of high-recurrence genital herpes, during the first half of 2024 and look forward to moving a second program candidate into the clinic by the end of 2024.”

Assembly Bio’s expanded virology research pipeline unveiled in 2022 focuses on differentiated programs against validated clinical targets for HBV/hepatitis delta virus (HDV) and herpesviruses. With the reprioritization of programs, Assembly Bio’s estimated cash runway extends into the third quarter of 2024.

4334 Clinical Data and Development Update
The Phase 1a clinical trial for 4334 (Study ABI-4334-101) is a randomized, blinded and placebo-controlled study evaluating the safety, tolerability and pharmacokinetics (PK) of 4334 following single ascending dose and multiple ascending dose administration in healthy subjects. The objectives of the study include assessment of the proportion of subjects with adverse events (AEs), premature treatment discontinuation due to AEs and abnormal laboratory results.

Dosing has been completed for all subjects in all four single-dose cohorts (30 mg, 100 mg, 200 mg and 400 mg), two multiple-dose cohorts of 100 mg and 200 mg and one food effect cohort at 200 mg (with data pending for the food effect cohort).

Based on data available for the single-dose and multiple-dose cohorts through April 17, 2023, 4334 continued to show a half-life supportive of once-a-day (QD) dosing. In addition, based on PK data from these cohorts and preclinical studies, daily minimum plasma trough concentrations (C_{min}) are projected to achieve double-digit multiples over protein-adjusted EC_{50} for both antiviral activity and against cccDNA formation within the dose range studied in the Phase 1a study, with the 200 mg QD dose projected to achieve >30 times the protein-adjusted EC_{50} for cccDNA formation.

Through April 17, 2023, treatment-emergent AEs and laboratory abnormalities were mild to moderate with the majority being mild, and there were no patterns of AEs or laboratory abnormalities noted to be associated with 4334 and no clinically significant ECG abnormalities reported.

4334 was internally discovered and developed by Assembly Bio and designed to optimize potency against both new virus

production and formation of cccDNA, the viral reservoir.

About Assembly Biosciences
Assembly Biosciences is a clinical-stage biotechnology company dedicated to the development of innovative small molecule antiviral therapeutics designed to change the path of serious viral diseases and improve the lives of patients worldwide. The company's hepatitis B virus (HBV) and hepatitis delta virus (HDV) pipeline includes two complementary approaches, a viral entry inhibitor and an oral, liver-focused, interferon-alpha receptor agonist, with potential application for both HBV and as chronic suppressive therapy for HDV, which is associated with significantly increased disease burden for HBV/HDV patients. The herpesvirus pipeline addresses two serious consequences associated with herpesvirus infections, high-recurrence genital herpes and transplant-associated herpesviruses. The company is also evaluating partnering options to further clinical development of its potent, next-generation HBV core inhibitors designed to disrupt the virus' replication cycle at several key points with the aim of achieving finite treatment and functional cures. 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 HBV, HDV and herpesvirus 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 clinical studies and fund business operations; 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 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; 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; 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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