Assembly Biosciences Doses First Participant in Phase 1a/b Clinical Trial of Herpes Simplex Virus Helicase-Primase Inhibitor Candidate ABI-5366

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– Phase 1a study portion of single ascending dosing in healthy participants will inform the development of ABI-5366 with interim data expected in Q3 2024 –

– Phase 1b study portion of multiple ascending weekly doses in participants with recurrent genital herpes on track to initiate by end of year with interim data expected in 1H 2025 –

SOUTH SAN FRANCISCO, Calif., June 10, 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 1a/b trial of its long-acting herpes simplex virus (HSV) helicase-primase inhibitor candidate ABI-5366.

ABI-5366, which is being developed for recurrent genital herpes, has demonstrated nanomolar potency against both HSV type 1 (HSV-1) and HSV type 2 (HSV-2) *in vitro* and its pharmacokinetic (PK) profile in preclinical studies strongly supports the potential for long-acting administration. Recurrent genital herpes caused by HSV-1 and HSV-2 is common after an initial symptomatic infection and affects an estimated four million individuals in the United States and European Union. Existing treatments are limited and only partially effective in controlling the infection or reducing transmission risk despite daily, chronic administration. In studies of individuals with highly recurrent genital herpes (six or more recurrences a year), only 34% remained recurrence free for a year while on current suppressive therapies.

“We are pleased to advance ABI-5366 into clinical development for recurrent genital herpes, a disease which significantly impacts the lives of millions of people, and where no new therapeutic options have been approved in over 25 years," said Anuj Gaggar, MD, PhD, chief medical officer of Assembly Bio. “Importantly, since the HSV helicase-primase is a clinically validated viral target, the PK data from healthy participants in the Phase 1a part of this study will enable us to assess the ability of ABI-5366 to achieve the target concentrations we have established for antiviral efficacy and to support a once-weekly oral dosing profile. These data will also inform our dose selection for the multiple ascending dose Phase 1b part of the study, where we will evaluate viral and clinical outcomes in individuals with recurrent genital herpes.”

About ABI-5366-101

ABI-5366-101 is a randomized, blinded and placebo-controlled Phase 1a/b clinical study of ABI-5366. Dosing has initiated for Part A in healthy participants, which will evaluate the safety, tolerability and PK of ABI-5366 following single ascending dose administration. Participants in Part A will be randomized 6:2 between ABI-5366 and placebo in up to five cohorts at different doses.

Assembly Bio plans to move directly into Part B in participants seropositive for HSV-2 with recurrent genital herpes, which will evaluate ABI-5366 in multiple ascending dose administration and is expected to initiate by the end of the year. Part B will evaluate a weekly oral dose of ABI-5366 for a 29-day dosing period. Participants in Part B will be randomized 20:5 between ABI-5366 and placebo in four cohorts, exploring four dose levels with a pooled placebo analysis.

In addition to assessing safety, tolerability and PK, Part B will also evaluate antiviral efficacy by measuring changes in viral parameters including viral shedding rate and HSV-2 DNA levels obtained from swab samples, and clinical parameters including lesion recurrence rate and lesion duration. The trial results will support dose selection for a future Phase 2 trial.

Additional information about the Phase 1a/b trial is available at clinicaltrials.gov using the identifier NCT06385327. Data from preclinical research supporting clinical advancement for ABI-5366 will be presented in a poster presentation at the 48th Annual International Herpesvirus Workshop, taking place in Portland, Ore., July 13-17, 2024.

ABI-5366 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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