Assembly Biosciences Reports Positive Interim Phase 1a Results from Clinical Trial Evaluating Long-Acting Helicase-Primase Inhibitor ABI-1179 in Development for Recurrent Genital Herpes

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– ABI-1179 was well-tolerated, with a half-life of approximately four days and high exposure across the dose range evaluated supporting the potential for once-weekly oral administration at a low dose –

– Assembly Bio to move ABI-1179 directly into Phase 1b portion of the ongoing Phase 1a/b study in participants with recurrent genital herpes –

– Phase 1b to run concurrently with ongoing Phase 1b study for ABI-5366, with interim data for both candidates anticipated in fall 2025 –

SOUTH SAN FRANCISCO, Calif., Feb. 20, 2025 (GLOBE NEWSWIRE) -- Assembly Biosciences, Inc. (Nasdaq: ASMB), a biotechnology company developing innovative therapeutics targeting serious viral diseases, today announced positive interim Phase 1a results in healthy participants from its ongoing Phase 1a/b study of ABI-1179, an investigational long-acting herpes simplex virus (HSV) helicase-primase inhibitor candidate for recurrent genital herpes.

A half-life of approximately four days and high exposure across the dose range evaluated exceeded Assembly Bio's targets for a once-weekly oral dosing profile. ABI-1179 was well-tolerated with a favorable safety profile observed. At all doses evaluated, including the lowest dose of 50 mg, ABI-1179 exceeded Assembly Bio's target plasma concentrations for antiviral activity, a target established from pharmacokinetic (PK) modelling and projected to achieve increased efficacy compared to approved therapies.

With these data, Assembly Bio plans to move directly into the Phase 1b portion of the ABI-1179 study in participants with recurrent genital herpes. This Phase 1b study will be conducted concurrently with the ongoing Phase 1b evaluation of ABI-5366, Assembly Bio's other long-acting helicase-primase inhibitor candidate that began dosing in Phase 1b in the fourth quarter of 2024. The studies are anticipated to be conducted at the same sites using equivalent eligibility criteria and outcome measures for both candidates. Assembly Bio plans to report interim data for both candidates together in fall 2025 given adjustments to enrollment timelines that will enable the studies to run concurrently.

"Millions of people live with life-altering symptoms of recurrent genital herpes, and these symptoms are not well-managed by available treatments," said Jason Okazaki, chief executive officer and president of Assembly Bio. "Unfortunately, no new therapeutic innovation has been made in decades. In Phase 1a, ABI-1179 and ABI-5366 both exceeded our target pharmacokinetic profile for our long-acting helicase-primase inhibitor program, and we are pleased to advance these two promising candidates with the potential to improve treatment outcomes for individuals with recurrent genital herpes. We look forward to reporting Phase 1b interim data for both candidates this fall, which will inform critical next steps in our data-driven portfolio strategy for this important indication."

ABI-1179 was contributed by Gilead Sciences, Inc. (Gilead) under the collaboration between Assembly Bio and Gilead. ABI-1179 and ABI-5366 are investigational product candidates that have not been approved anywhere globally, and their safety and efficacy have not been established.

Study ABI-1179-101 – Phase 1a Interim Results

Study Overview

ABI-1179-101 is a randomized, blinded and placebo-controlled Phase 1a/b clinical study of ABI-1179. Part A (Phase 1a) is ongoing, evaluating the safety, tolerability and PK of ABI-1179 following single ascending dose administration in healthy participants. Dosing is complete for three cohorts in Part A, evaluating doses of 50 mg, 100 mg and 300 mg, with each cohort randomized 6:2 between ABI-1179 and placebo. The study protocol includes a food effect cohort, which has not yet been conducted.

Safety and PK data reported here reflect data available as of the cut-off date, which reflects a follow-up period ranging by cohort from five days to the full follow-up period of 11 days after dosing. The study remains blinded and the reported interim safety data include data from both active and placebo treatment groups collectively.

Results

Across the Part A (Phase 1a) cohorts evaluated to date, ABI-1179 had a mean half-life of approximately four days when dosed orally, supporting once-weekly oral dosing, the target profile for ABI-1179. ABI-1179 is projected to maintain the target plasma concentrations for antiviral activity established by PK modelling at a low oral weekly dose.

In these cohorts to date, ABI-1179 was well-tolerated with a favorable safety profile observed. Treatment-emergent adverse events (AEs) were all mild in intensity and all were considered not related to study treatment by the study investigators; there were no serious AEs in any dose cohort. One self-limited grade 2 alanine transaminase (ALT) elevation was observed in the cohort evaluating the highest dose of 300 mg. There were no treatment-related grade 3 or 4 laboratory abnormalities and no protocol-defined stopping criteria were met. There were no clinically significant ECG abnormalities or patterns of AEs or laboratory abnormalities noted.

Study ABI-1179-101 – Phase 1b Design

Assembly Bio has initiated preparatory activities for Part B (Phase 1b) in participants seropositive for HSV type 2 (HSV-2) with recurrent genital herpes, which will evaluate multiple ascending doses of ABI-1179. Part B of the study will evaluate weekly oral dose administration of ABI-1179 over a 29-day treatment interval in up to four cohorts. Participants in Part B will be randomized 20:5 between ABI-1179 and placebo in each cohort, with a pooled analysis of placebo recipients.

In addition to assessing safety, tolerability and PK, Part B will also evaluate antiviral activity by assessing changes in viral parameters including HSV-2 shedding rate and levels of virus obtained from genital swab samples. Effects on clinical parameters including lesion recurrence rate and lesion duration will also be measured.

Additional information about the Phase 1a/b trial is available at clinicaltrials.gov using the identifier NCT06698575. Assembly Bio expects to submit complete data from the trial for presentation at future scientific meetings.

About Recurrent Genital Herpes
Genital herpes is a chronic viral infection caused by the herpes simplex virus (HSV) that can result in painful genital lesions, serious psychological and social impacts, and an increased risk of acquiring human immunodeficiency virus (HIV). Most people with initial symptomatic genital HSV type 2 (HSV-2) infection have three or more recurrences per year, including over four million people in the United States and France, Germany, Italy, Spain and the United Kingdom. While genital herpes can be caused by either HSV type 1 (HSV-1) or HSV-2, recurrences are more likely to be experienced by individuals infected by HSV-2. The current standard of care for recurrent genital herpes is nucleoside analogs given intermittently for recurrences or as daily chronic suppressive therapy; however, these are only partially effective in preventing recurrences and in reducing transmission of the virus. No new drugs have been approved in the United States or Europe to treat genital herpes for more than 25 years.

About Helicase-Primase Inhibition
HSV helicase-primase inhibitors target the viral helicase-primase complex, an essential viral enzyme complex that is conserved across both HSV-1 and HSV-2 and has no host equivalent. Inhibition of the helicase-primase complex is a clinically validated mechanism that has shown the potential for superior efficacy to nucleoside analogs in short-duration clinical studies in participants with recurrent genital herpes.

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 maintain financial resources necessary to continue its research activities, clinical studies and other business operations; 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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