Assembly Biosciences Presents Interim Phase 1b Data for HSV Helicase-Primase Inhibitor Candidate ABI-5366 at the 38th Congress of the International Union Against Sexually Transmitted Infections (IUSTI)- Europe

October 10, 2025

– Late-breaking oral presentation highlights interim Phase 1b data reported earlier this year for two cohorts in participants with recurrent genital herpes –

– Statistically significant reductions in HSV-2 shedding rate, high viral load shedding rate and genital lesion rate observed in the cohort evaluating 350 mg weekly oral dose compared to placebo –

– Interim data evaluating a monthly dosing regimen of ABI-5366 and weekly dosing for second HSV helicase-primase inhibitor candidate ABI-1179 expected to be shared later this fall –

SOUTH SAN FRANCISCO, Calif., Oct. 10, 2025 (GLOBE NEWSWIRE) -- Assembly Biosciences, Inc. (Nasdaq: ASMB), a biotechnology company developing innovative therapeutics targeting serious viral diseases, today announced that interim Phase 1b clinical data for its long-acting herpes simplex virus (HSV) helicase-primase inhibitor candidate ABI-5366 are featured in a late-breaking oral presentation during the 38th Congress of the International Union Against Sexually Transmitted Infections (IUSTI)- Europe, taking place October 9-11, 2025, in Athens, Greece.

"We are pleased to share this first scientific presentation of the interim Phase 1b data for ABI-5366, including highly potent antiviral activity, that we announced earlier this year," said Anuj Gaggar, MD, PhD, chief medical officer of Assembly Bio. "These results highlight the potential to reduce viral shedding rates and the burden of recurrent genital lesions with a weekly oral dose of ABI-5366. Given that current treatment options for recurrent genital herpes are limited with no new therapies approved in more than two decades, we are rapidly advancing ABI-5366 toward Phase 2 studies to support our goal of delivering better treatment options and meaningful benefits to the millions of individuals living with this disease."

The late-breaking oral presentation titled "Safety, pharmacokinetics and antiviral activity of ABI-5366, a novel, oral, long-acting HSV helicase-primase inhibitor in subjects with recurrent genital herpes: interim data from a phase 1b study" highlights positive interim data from the first two cohorts of participants with recurrent genital herpes. The first cohort received a 150 mg loading dose and weekly doses of 30 mg while the second cohort received weekly doses of 350 mg. ABI-5366 was observed to be well tolerated at both doses evaluated.

In the 350 mg weekly dosing cohort, statistically significant reductions were observed compared to placebo for HSV type 2 (HSV-2) shedding rate, which decreased by 94%, high viral load shedding rate, which decreased by 98%, and genital lesion rate, which decreased by 94%. The observed pharmacokinetic profile continues to support weekly and potentially monthly dosing of ABI-5366.

A monthly oral dosing regimen of ABI-5366 is currently being evaluated in the ongoing Phase 1b study. In addition, a Phase 1b study evaluating weekly dosing of ABI-1179, another long-acting HSV helicase-primase inhibitor candidate, is being conducted concurrently. Assembly Bio anticipates sharing interim data from both studies later this fall and expects to initiate Phase 2 clinical studies of ABI-5366 in mid-2026.

Assembly Bio intends to make the presentation materials available on the "Events & Presentations" page in the "Investors" section and on the "Publications" page in the "Pipeline" section of its website at www.assemblybio.com.

Under the collaboration agreement between Assembly Bio and Gilead Sciences, Inc. (Gilead), Gilead has the right to opt in to an exclusive license for further development and commercialization of the helicase-primase inhibitor program after reviewing the option data package to be delivered by Assembly Bio following completion of the Phase 1b studies.

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

About Recurrent Genital Herpes

Genital herpes is a chronic viral infection caused by HSV that can result in painful genital lesions, serious psychological and social impacts, and an increased risk of acquiring human immunodeficiency virus (HIV). Epidemiologic studies estimate over four million

people in the United States and France, Germany, Italy, Spain and the United Kingdom experience recurrent genital herpes, with most people with initial symptomatic genital HSV-2 infection having three or more recurrences per year. 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 the current standard of care, 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 and secure additional funding 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. (Gilead), 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 may not differentiate Assembly Bio's product candidates from other companies' candidates; potential effects of changes in government regulation, including as a result of the change in U.S. administration in 2025; 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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