Assembly Biosciences Presents Data Highlighting Recurrent Genital Herpes Program at STI & HIV 2025 World Congress and International Herpesvirus Workshop

July 26, 2025

– Phase 1a clinical data in healthy participants presented for both ABI-5366 and ABI-1179, novel long-acting herpes simplex virus helicase-primase inhibitor candidates –

– Preclinical data and U.S. genital herpes prevalence and treatment patterns also highlighted –

– Interim proof-of-concept Phase 1b data in participants with recurrent genital herpes expected for both candidates in fall 2025 –

SOUTH SAN FRANCISCO, Calif., July 26, 2025 (GLOBE NEWSWIRE) -- Assembly Biosciences, Inc. (Nasdaq: ASMB), a biotechnology company developing innovative therapeutics targeting serious viral diseases, today announced Phase 1a clinical and preclinical data for its herpes simplex virus (HSV) helicase-primase inhibitor candidates ABI-5366 and ABI-1179 are featured in multiple poster presentations, including one late-breaker, during the STI & HIV 2025 World Congress, taking place July 26-30, 2025, in Montreal, Canada, as well as in oral and poster presentations at the 49th Annual International Herpesvirus Workshop, taking place July 26-30, 2025, in Berlin, Germany.

“These data presented for ABI-5366 and ABI-1179 continue to support the promise of both candidates to provide important innovation that could improve quality of life for people living with recurrent genital herpes,” said Anuj Gaggar, MD, PhD, chief medical officer of Assembly Bio. “This includes the potential for once weekly, and in the case of ABI-5366, once monthly, oral dosing. These dosing options would represent a meaningful reduction in treatment burden from current standard of care therapies that require daily dosing. Both candidates are now in Phase 1b clinical evaluation in participants with recurrent genital herpes, and we look forward to sharing interim data, including antiviral activity, from these studies this fall.”

At the STI & HIV 2025 World Congress, two posters highlight the safety and pharmacokinetic (PK) profiles of ABI-5366 and ABI-1179 as observed in healthy participants in Phase 1a studies, supporting their progression to Phase 1b evaluation. The late-breaking poster for ABI-1179, the first scientific presentation of Phase 1a clinical data for this candidate, includes additional new interim data showing that, as was also the case in the ABI-5366 Phase 1a study, no clinically significant food effect was observed. Unblinded safety data for ABI-1179 are also included in this presentation.

Additional posters presented at STI & HIV 2025 review previously presented preclinical studies of ABI-5366 and provide additional methodology for the retrospective analysis of claims data estimating the prevalence of genital herpes and treatment patterns in the U.S. presented earlier this year.

At the 49th Annual International Herpesvirus Workshop, one poster presentation and one oral presentation describe the preclinical profiles of ABI-5366 and ABI-1179 and include interim safety and PK data for both candidates from the Phase 1a studies in healthy participants.

Titles of the presentations are listed below. Assembly Bio intends to make the posters 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.

STI & HIV 2025 World Congress

- **Oral Poster Presentation:** ABI-5366, a novel, oral, long-acting herpes simplex virus helicase-primase inhibitor: interim safety and pharmacokinetic results from a phase 1a study in healthy participants
- **Oral Poster Presentation**: ABI-5366, a potent HSV helicase-primase inhibitor, with potential for weekly or monthly oral dosing for recurrent genital herpes
- **Poster Presentation:** Estimating genital herpes prevalence and treatment patterns among U.S. healthcare-engaged individuals: insights from claims data
- **Late-Breaker Poster Presentation:** ABI-1179, a novel, orally administered, long-acting HSV helicase-primase inhibitor: interim analysis of safety and pharmacokinetic data from a phase 1a study in healthy participants

49th Annual International Herpesvirus Workshop

- **Oral and Poster Presentations:** ABI-5366 and ABI-1179, two potent, long-acting helicase-primase inhibitors for the treatment of recurrent genital herpes

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. ABI-1179 was contributed by Gilead Sciences, Inc. (Gilead) under the collaboration between Assembly Bio and Gilead.

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). 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 type 2 (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 treatment 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 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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