Assembly Biosciences Presents New Data Highlighting Long-Acting Herpes Simplex Virus Candidate ABI-5366 and Genital Herpes Prevalence and Treatment Patterns at the 2025 ESCMID Congress

April 9, 2025

– Clinical and preclinical data supporting dosing profile and tolerability for ABI-5366, a novel long-acting helicase-primase inhibitor candidate, featured in two poster presentations –

– Additional poster presentation highlights new insights in genital herpes prevalence and treatment patterns in the U.S. –

– ABI-5366 is currently being evaluated in ongoing Phase 1b clinical trial with interim proof-of-concept data expected in fall 2025 –

SOUTH SAN FRANCISCO, Calif., April 09, 2025 (GLOBE NEWSWIRE) -- Assembly Biosciences, Inc. (Nasdaq: ASMB), a biotechnology company developing innovative therapeutics targeting serious viral diseases, today announced data from its herpes simplex virus (HSV) program featured in three poster presentations at the 2025 Congress of the European Society of Clinical Microbiology and Infectious Diseases (ESCMID) taking place in Vienna, Austria, on April 11-15, 2025.

"We are encouraged by the data shared from our clinical and preclinical studies of ABI-5366, supporting its potential to be a once-weekly or once-monthly oral treatment option for those with recurrent genital herpes, an underserved disease space," said Anuj Gaggar, MD, PhD, chief medical officer of Assembly Bio. "Importantly, our analysis of genital herpes prevalence and treatment patterns further underscores the substantial burden of genital herpes in the United States and wide variability in antiviral treatment patterns. This guides our efforts to improve therapeutic options in a field that has seen little innovation for decades."

ABI-5366: a Long-Acting Helicase-Primase Inhibitor Candidate for Recurrent Genital Herpes

The ePoster entitled "*The safety and pharmacokinetics of ABI-5366, a novel, oral, long-acting HSV helicase-primase inhibitor: Interim results from a Phase 1a/1b study in healthy participants*" showcases clinical data from a single-dose Phase 1a evaluation of safety and pharmacokinetics (PK) of ABI-5366 in healthy participants. Results demonstrate that ABI-5366 was well tolerated when administered orally up to 350 mg with no Grade 3 or 4 treatment-related laboratory abnormalities or serious adverse events (AEs) reported. Further, an observed half-life of approximately 20 days across all dosing cohorts supports the potential for once-weekly or once-monthly oral administration.

Additionally, the poster entitled "*Preclinical profile of ABI-5366, a novel potent HSV helicase-primase inhibitor, with potential for weekly or monthly oral dosing for the treatment of recurrent genital herpes*" highlights results from preclinical studies of ABI-5366, in which broad activity against both HSV type 1 (HSV-1) and HSV type 2 (HSV-2) clinical isolates was observed. Preclinical data also reinforce a PK profile supportive of the potential for once-weekly or once-monthly oral dosing and demonstrate distribution of ABI-5366 to tissues relevant to HSV infection.

ABI-5366 is being evaluated in the Phase 1b portion of an ongoing Phase 1a/b study in participants with recurrent genital herpes. Assembly Bio expects to report interim Phase 1b data for both ABI-5366 and ABI-1179, a second long-acting helicase-primase inhibitor candidate, in fall 2025.

Genital Herpes Prevalence and Treatment Patterns

The poster entitled "*Estimating Genital Herpes Prevalence and Treatment Patterns Among U.S. Healthcare-Engaged Individuals: Insights from Claims Data*" features results from a retrospective analysis of data from Forian's hybrid claims ecosystem and electronic health record (EHR) database, CHRONOS, of more than 40 million individuals to estimate genital herpes prevalence and treatment patterns. The analysis identified an estimated 262,457 total genital herpes cases and 148,067 recurrent cases in 2023 among the study sample, with the highest prevalence observed among females and those aged 18-39. These estimates reflect ICD-10-CM codes and symptom capture in a defined time period using a study sample of individuals engaged in the healthcare system. Extrapolated to the U.S. population, approximately 1.35 million individuals were estimated to experience recurrent genital herpes, with over 800,000 individuals estimated to receive chronic or intermittent suppressive therapy.

Among all genital herpes patients, an estimated 32% were classified as receiving suppressive therapy (including both chronic and intermittent), 40% episodic therapy and 28% no interventions. Among recurrent cases, an estimated 97% were classified as receiving pharmacologic treatment with 57% classified as receiving suppressive therapy and 40% episodic therapy, supporting the potential for better treatment strategies to enhance chronic disease management.

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

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. 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). Most people with initial symptomatic genital HSV type 2 (HSV-2) infection have three or more recurrences per year, with epidemiologic studies estimating over four million people in the United States and France, Germany, Italy, Spain and the United Kingdom experience recurrent genital herpes. 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 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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