Assembly Biosciences Doses First Participant in Phase 1b Portion of Phase 1a/b Clinical Trial of Investigational Long-Acting Herpes Simplex Virus Helicase-Primase Inhibitor ABI-1179

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– Study will evaluate safety and antiviral activity of ABI-1179 in participants with recurrent genital herpes –

– ABI-1179 IND cleared to support study expansion to sites in United States –

– Phase 1b studies for ABI-1179 and ABI-5366 running concurrently with interim data for both candidates on track for fall 2025 –

SOUTH SAN FRANCISCO, Calif., June 30, 2025 (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 1b portion of the Phase 1a/b study of its long-acting herpes simplex virus (HSV) helicase-primase inhibitor candidate ABI-1179.

The Phase 1b study will evaluate the safety and antiviral activity of weekly oral doses of ABI-1179 over a 29-day treatment period in participants with recurrent genital herpes. Antiviral activity will be evaluated by assessing changes in viral parameters, including HSV type 2 (HSV-2) shedding rate and levels of HSV-2 DNA. Effects on clinical parameters including days with lesions will also be measured. ABI-1179 demonstrated positive interim Phase 1a results with a pharmacokinetic (PK) profile supporting once-weekly oral dosing in healthy participants and has exhibited low nanomolar potency against both HSV type 1 (HSV-1) and HSV-2 *in vitro*.

Assembly Bio has advanced both ABI-5366 and ABI-1179 into Phase 1b studies after each long-acting helicase-primase inhibitor candidate exceeded the company's target PK profiles in Phase 1a evaluation in healthy participants. The Phase 1b studies utilize equivalent eligibility criteria and outcome measures and are being conducted at overlapping sites. To maintain enrollment timelines while running both trials concurrently, Assembly Bio has received clearance for an Investigational New Drug application (IND) for ABI-1179 to support expansion of this Phase 1b study to sites in the United States. The studies for both candidates are on track to report interim data in fall 2025.

"For the millions of individuals affected by recurrent genital herpes, current therapies fall short in managing the significant impact repeated outbreaks have on their lives," said Anuj Gaggar, MD, PhD, chief medical officer of Assembly Bio. "With the Phase 1b study of ABI-1179 now underway, we look forward to evaluating viral and clinical outcomes for both promising long-acting HSV investigational therapies, ABI-5366 and ABI-1179, and we remain on track for interim data from both studies in the fall of this year."

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 ABI-1179 and ABI-5366 after reviewing the Phase 1b data package to be delivered by Assembly Bio following completion of the studies.

About ABI-1179-101

ABI-1179-101 is a randomized, blinded, placebo-controlled Phase 1a/b clinical study of ABI-1179. Interim data has been reported for Part A (Phase 1a), evaluating the safety, tolerability and PK of ABI-1179 following single dose administration in healthy participants randomized 6:2 between ABI-1179 and placebo in up to five cohorts at different dose levels. Dosing has also initiated for Part B (Phase 1b) in participants seropositive for HSV-2 with recurrent genital herpes, which will evaluate weekly oral doses over a 29-day dosing period. Participants in Part B will be randomized 20:5 between ABI-1179 and placebo in up to four cohorts, exploring different dose levels with a pooled placebo analysis.

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

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

ABI-1179 was contributed by 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.

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 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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