Assembly Biosciences Presents New Preclinical Data Highlighting Investigational Helicase-Primase Inhibitors at International Herpesvirus Workshop

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– Data from both ABI-5366 and ABI-1179, novel long-acting helicase-primase inhibitor candidates for recurrent genital herpes, to be presented –

– Poster presentation highlights key preclinical data from ABI-5366 supporting its entry into ongoing Phase 1a/b clinical trials –

– Oral and poster presentations feature first data presented from ABI-1179, expected to enter the clinic by the end of 2024 –

SOUTH SAN FRANCISCO, Calif., July 15, 2024 (GLOBE NEWSWIRE) -- Assembly Biosciences, Inc. (Nasdaq: ASMB), a biotechnology company developing innovative therapeutics targeting serious viral diseases, today announced new preclinical data from its investigational herpes simplex virus (HSV) portfolio featured in three presentations at the International Herpesvirus Workshop (IHW), taking place July 13-17, 2024, in Portland, Ore.

“We are excited to present promising data from our HSV helicase-primase inhibitor candidates ABI-5366 and ABI-1179, which we are rapidly progressing to deliver on our mission of offering new, effective treatments for people living with chronic viral diseases,” said Anuj Gaggar, MD, PhD, chief medical officer of Assembly Bio. “Current treatments for recurrent genital herpes often fall short in fully managing symptoms and preventing recurrences, and we are pleased with the potential of our HSV candidates to provide a different approach, as highlighted in the data presented at IHW. We continue to advance these candidates and look forward to sharing further updates with the herpesvirus community, including interim ABI-5366 Phase 1a first-in-human data expected in the third quarter of this year.”

Approximately 50% of individuals with initial symptomatic genital herpes infection have three or more recurrences per year, including over four million people in the United States and France, Germany, Italy and Spain (collectively, the EU4), and the United Kingdom. While genital herpes can be caused by either HSV type 1 (HSV-1) or HSV type 2 (HSV-2), recurrences are more likely to be experienced by individuals infected by HSV-2. The current standard of care for recurrent genital herpes are nucleoside analogs; however, these are only partially effective in preventing recurrences. Assembly Bio’s HSV antiviral candidates target the HSV helicase-primase complex, an essential HSV enzyme complex with no host equivalent, and are designed for long-acting administration.

A poster entitled “The Helicase-Primase Inhibitor ABI-5366 Is a Novel, Potent, Long-Acting Inhibitor for the Treatment of Recurrent Genital Herpes” highlights preclinical data that supported ABI-5366’s entry into Phase 1 clinical evaluation. Results demonstrated that ABI-5366 showed low nanomolar activity against both HSV-1 and HSV-2, including broad activity against HSV clinical isolates, and specificity for HSV. ABI-5366 was shown to be generally non-toxic across a variety of cell types with no off-target effects observed *in vitro* or *in vivo,* including no activity against carbonic anhydrase esterases. Further, a favorable *in vivo* safety profile of ABI-5366 was observed in 28-day oral toxicity studies in two species, and pharmacokinetic (PK) studies evaluating ABI-5366 when administered orally or intramuscularly demonstrated long-acting potential for this compound. The Phase 1a/b study for ABI-5366 was initiated in May 2024 and is currently enrolling; interim Phase 1a data are expected in Q3 2024 and interim Phase 1b data are expected in the first half of 2025.

Additionally, an oral and poster presentation entitled “Preclinical Characterization of ABI-1179, a Potent Helicase Primase Inhibitor for the Treatment of Recurrent Genital Herpes” features preclinical data from ABI-1179, a structurally distinct, long-acting helicase-primase inhibitor candidate, licensed from Gilead Sciences, Inc. (Gilead) under the collaboration between Assembly Bio and Gilead. ABI-1179 has demonstrated low nanomolar activity across HSV-1 and HSV-2 lab strains and clinical isolates, including acyclovir-resistant isolates. In resistance selection studies, ABI-1179 displayed a higher barrier to resistance development than acyclovir. Furthermore, ABI-1179 demonstrated antiviral activity against some HSV-2 strains harboring mutations known to confer resistance to other helicase-primase inhibitors. In a preclinical study, ABI-1179 demonstrated a favorable PK profile that supports the evaluation of once-weekly oral dosing. Further, in a preclinical model of recurrent HSV infection, ABI-1179 significantly reduced the development of recurrent lesions. Assembly Bio expects to initiate a Phase 1a/b first-in-human study of ABI-1179 by the end of 2024.

Assembly Bio intends to make the presentations available on the “Events & Presentations” page in the “Investors” section of its website at www.assemblybio.com. The investigational product candidates ABI-5366 and ABI-1179 have not been approved anywhere globally, and their safety and efficacy have not been established.

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 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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