Assembly Biosciences Announces $30.1 Million Equity Investment and Accelerated Funding from Gilead to Advance Clinical Development Programs

December 19, 2024

—Assembly Bio to receive approximately $20.1 million equity investment and $10 million in accelerated funding under the collaboration, extending cash runway to mid-2026—

—Additional equity investment raises Gilead's ownership stake in Assembly Bio to 29.9%—

–Funding supports pipeline progress, including amendment to accelerate clinical development of Assembly Bio's novel small molecule hepatitis D virus candidate ABI-6250—

SOUTH SAN FRANCISCO, Calif., Dec. 19, 2024 (GLOBE NEWSWIRE) -- Assembly Biosciences, Inc. (Nasdaq: ASMB), a biotechnology company developing innovative antiviral therapeutics targeting serious viral diseases, today announced an equity investment of $20.1 million by Gilead Sciences, Inc. ("Gilead") to purchase additional Assembly Bio common stock and an amendment to their collaboration to advance the research and development of novel antiviral therapies with $10 million in accelerated funding. With the new equity investment, Gilead increases its equity ownership of Assembly Bio to 29.9%.

Funding received from Gilead will support the advancement of Assembly Bio's clinical pipeline of antiviral therapeutic candidates for herpesviruses, hepatitis D virus (HDV) and hepatitis B virus (HBV). Assembly Bio expects to release data from multiple ongoing clinical studies in the coming year, including the interim Phase 1b proof-of-concept data readout for ABI-5366 projected for the first half of 2025.

The amendment to the collaboration agreement adjusts the option timepoints and option payment structure for ABI-6250, an orally bioavailable viral entry inhibitor for the treatment of HDV, to support updated clinical strategies to accelerate and optimize program development. As part of this amendment, $10 million of option-related payments for this program have been accelerated.

"Gilead's further investment strengthens our balance sheet as we look ahead to multiple key clinical data readouts for our novel antiviral candidates in 2025," said Jason Okazaki, chief executive officer and president of Assembly Bio. "In addition, we expect our updated clinical plan for ABI-6250 to significantly reduce the development timeline for the compound. Together, the amendment and additional investment will help advance our programs expeditiously and highlight the collective efforts of our organizations to change the treatment paradigm for people affected by serious viral diseases."

Since the collaboration with Gilead was announced in October 2023, Assembly Bio has initiated clinical studies for four small molecule antiviral candidates. In mid-2024, a Phase 1a/b study for ABI-5366, a long-acting helicase-primase inhibitor for treatment of recurrent genital herpes and a Phase 1b study for ABI-4334, a next-generation capsid assembly modulator for treatment of chronic HBV infection, were initiated. In December 2024, Assembly Bio initiated dosing in the Phase 1a portion of a Phase 1a/b study for ABI-1179, a long-acting helicase-primase inhibitor for treatment of recurrent genital herpes contributed by Gilead under the collaboration, and has received regulatory clearance for a Phase 1a study for ABI-6250.

Terms of the amendment and equity purchase

Assembly Bio will receive $10 million in accelerated funding under the collaboration agreement and a $20.1 million equity investment from Gilead. This equity investment at a premium will increase the percentage of the outstanding voting stock of Assembly Bio owned by Gilead from approximately 19.9% to 29.9% as of the date of closing.

The accelerated funding amount reflects a portion of option-related payments that Assembly Bio is eligible to receive for ABI-6250 and will be creditable against future payments under the collaboration agreement. In addition, Gilead and Assembly Bio have amended the option-related payments and option timepoints for this program to support potential accelerated development strategies. The scope of Gilead's option and Assembly Bio's right to opt-in to share profits and costs in the United States are unchanged.

With the accelerated $10 million payment resulting from the collaboration amendment and the $20.1 million additional equity investment, Assembly Bio expects its cash runway to extend to mid-2026.

ABI-5366, ABI-1179, ABI-4334 and ABI-6250 are investigational and not approved anywhere globally. Their efficacy and safety have not been established. More information about clinical trials with ABI-5366, ABI-1179, ABI-4334 and ABI-6250 is available at www.clinicaltrials.gov.

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.

Contacts

Investor and Corporate:
Shannon Ryan
SVP, Investor Relations, Corporate Affairs and Alliance Management
(415) 738-2992
investor_relations@assemblybio.com

Media:
Sam Brown Inc.
Hannah Hurdle
(805) 338-4752
ASMBMedia@sambrown.com