Assembly Biosciences Nominates Development Candidate ABI-6250, an Orally Bioavailable HDV Entry Inhibitor

October 2, 2023

− ABI-6250 demonstrated low nanomolar potency against hepatitis D virus and selective inhibition of NTCP in preclinical studies with once-daily dosing projected –

− Progression into clinical studies planned by the end of 2024 –

SOUTH SAN FRANCISCO, Calif., Oct. 02, 2023 (GLOBE NEWSWIRE) -- Assembly Biosciences, Inc. (Nasdaq: ASMB), a biotechnology company developing innovative antiviral therapeutics targeting serious viral diseases, today announced the selection of development candidate ABI-6250 to progress to IND-enabling studies. ABI-6250, an orally bioavailable small molecule entry inhibitor, is the first development candidate nominated by the company for the treatment of chronic hepatitis D virus (HDV) infection, and the second development candidate selected in 2023, following ABI-5366 for high-recurrence genital herpes.

“We’re pleased to nominate ABI-6250 as a development candidate targeting chronic HDV infection, the most severe form of viral hepatitis,” said William Delaney, PhD, chief scientific officer of Assembly Bio. “Current treatment options for HDV patients are limited and the only approved therapeutic requires daily injections. We are excited to bring ABI-6250 forward into IND-enabling studies with the goal of providing the first oral chronic therapy for HDV patients.”

HDV is a virus that infects liver cells in people who are also infected with hepatitis B virus (HBV). Patients with chronic HDV infection experience much higher rates of cirrhosis and liver cancer than those with chronic HBV infection only. In preclinical studies, ABI-6250 inhibited the interaction of HDV with sodium taurocholate co-transporting polypeptide (NTCP), the host receptor used by HBV/HDV to enter liver cells. Inhibiting viral entry by blocking NTCP is a clinically validated target for reducing HDV viremia and liver injury in patients.

In preclinical studies, ABI-6250 demonstrated low nanomolar potency against all tested HBV/HDV genotypes, favorable selectivity for NTCP versus other bile acid transporters, good oral bioavailability and a pharmacokinetic profile projected to support once-daily oral dosing. Assembly Bio plans to present data for ABI-6250 at future scientific conferences.

About Assembly Biosciences
Assembly Biosciences is a biotechnology company dedicated to the development of innovative small molecule antiviral 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 clinical studies and fund business operations; Assembly Bio’s ability to initiate and complete clinical studies involving its therapeutic product candidates, including studies contemplated by Assembly Bio’s collaboration agreements, in the currently anticipated timeframes; 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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