Assembly Bio Announces Decision to Discontinue Clinical Development of ABI-H2158

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--Decision follows observation of elevated alanine transaminase (ALT) levels in Phase 2 study
--Company will focus on advancing ongoing triple combination studies and earlier pipeline candidates

SOUTH SAN FRANCISCO, Calif., Sept. 01, 2021 (GLOBE NEWSWIRE) -- Assembly Biosciences, Inc. (Nasdaq: ASMB), a clinical-stage biotechnology company developing innovative therapeutics targeting hepatitis B virus (HBV), today announced its decision to discontinue development of ABI-H2158 (2158) following the observation of elevated ALT levels consistent with drug-induced hepatotoxicity in an ongoing Phase 2 trial.

“Patient safety is always our priority, which is why we have elected to discontinue the development of 2158,” said John McHutchison, AO, MD, chief executive officer and president of Assembly Bio. “We remain committed to our pursuit of developing finite and curative therapies for individuals with chronic hepatitis B, and our strategy remains unchanged. We will continue to evaluate our core inhibitor portfolio, to ultimately choose the best and safest candidate to take forward into later stage clinical trials as we believe this mechanism will be an important and key component of future curative regimens. We remain focused on expeditiously advancing our additional clinical programs, including the two ongoing Phase 2 triple combination studies, accelerating the clinical development for 3733 and 4334, and progressing additional research programs in our HBV portfolio with complementary mechanisms. And, as always, we will continue evaluating strategic opportunities to build additional value in the company’s pipeline.”

The Phase 2 clinical study for 2158 is a multi-center, randomized, placebo-controlled trial in treatment-naïve patients with HBeAg positive or HBeAg negative chronic hepatitis B infection without cirrhosis. A total of 88 patients were enrolled and randomized three-to-one to receive either 300 mg 2158 plus entecavir or placebo plus entecavir once daily for up to 72 weeks. In the study, two patients receiving 2158 experienced Grade 4 elevations in ALT leading to drug discontinuation. Two additional patients also receiving 2158 developed Grade 3 ALT elevations. No alternate causes for the ALT elevations have been identified, and these four patients continue to be closely monitored. The company has communicated the findings with the U.S. Food & Drug Administration (FDA) and has voluntarily chosen to discontinue development of 2158 and the Phase 2 study. After communicating the company’s decision to the FDA, the FDA noted that 2158 would also be placed on clinical hold.

Assembly Bio maintains a deep pipeline of investigational core inhibitor candidates. The most advanced core inhibitor candidate, vebicorvir (VBR), has demonstrated favorable safety and a potent antiviral profile in patients treated for up to 1.5 years in the Phase 2 program. VBR is being evaluated in two ongoing triple combination studies for which initial on-treatment data are anticipated during 2022. ABI-H3733 (3733) has completed its Phase 1a study and initial data is planned to be announced at an upcoming medical meeting. Additionally, the company expects to advance its recently-selected core inhibitor candidate ABI-4334 (4334) into clinical development in 2022. 4334 has a best-in-class preclinical profile with single-digit nanomolar potency against the production of new virus, as well as the formation of covalently closed circular DNA (cccDNA). Importantly, 3733 and 4334 are structurally distinct from 2158.

Assembly Bio will also continue to advance a research pipeline of programs focusing on HBV antiviral mechanisms beyond core inhibition. In a collaboration with Door Pharma, Assembly Bio is developing a novel class of HBV core protein modulators that have the potential to interfere with viral nucleic acid including cccDNA transcription. Additionally, the company has proprietary internal research programs underway for two novel targets.

By redirecting the company’s resources previously reserved for the 2158 program and its Phase 2 studies, Assembly Bio expects to be able to advance development of its next-generation assets more quickly, while simultaneously extending its cash runway into the second half of 2023.

About Assembly Biosciences
Assembly Bio is a clinical-stage biotechnology company committed to bringing finite and curative therapies to the 270 million people living with hepatitis B virus (HBV) worldwide. A pioneer in the development of a new class of potent, oral core inhibitor drug candidates, Assembly Bio’s approach aims to break the complex viral replication cycle of HBV to free patients from a lifetime of therapy. Assembly Bio’s strategy toward cure includes a leading portfolio of more potent, next-generation core inhibitors, proof-of-concept combination studies and a research program focused on the discovery of novel HBV targets. 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 initiate and complete clinical studies involving its HBV therapeutic product candidates, including studies contemplated by Assembly Bio's clinical collaboration agreements, in the currently anticipated timeframes; safety and efficacy data from clinical 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; continued development and commercialization of Assembly Bio's HBV product candidates, if successful, in the China territory will be dependent on, and subject to, Assembly Bio's collaboration agreement governing its activity in the China territory; Assembly Bio's ability to maintain financial resources necessary to continue its clinical studies and fund business operations; any impact that the COVID-19 pandemic may have on Assembly Bio's business and operations, including initiation and continuation of its clinical studies or timing of discussions with regulatory authorities; 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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