Assembly Biosciences Presents New Data at AASLD The Liver Meeting™ Highlighting the Progress of its HBV Core Inhibitor Portfolio

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Newly selected preclinical core inhibitor candidate, ABI-4334, demonstrates single-digit nanomolar potency against both pgRNA encapsidation and cccDNA formation

ABI-H3733 shows favorable pharmacokinetics and safety in Phase 1a study; Phase 1b study expected to begin in 2022

Vebicorvir Phase 2 open-label study data demonstrate the contribution of core inhibition to deepen viral suppression; Oral presentation scheduled for November 14 at 10 am ET

SOUTH SAN FRANCISCO, Calif., Nov. 12, 2021 (GLOBE NEWSWIRE) -- Assembly Biosciences, Inc. (Nasdaq: ASMB), a clinical-stage biotechnology company developing innovative therapeutics targeting hepatitis B virus (HBV), today reported preclinical data from the company's newly selected core inhibitor candidate, ABI-4334 (4334), and clinical results from the Phase 1a study of ABI-H3733 (3733) in healthy volunteers at the American Association for the Study of Liver Diseases (AASLD) The Liver Meeting™. New data from the Phase 2 study of its investigational candidate vebicorvir (VBR) will be highlighted in an oral presentation on Sunday, November 14 at 10 am ET.

"Through our core inhibitor research and development pipeline, we continue to generate data that validate core inhibitors as distinct and complementary treatments to standard-of-care nucleo(s)tide (NrtI) therapy in patients with HBV," said John McHutchison, AO, MD, chief executive officer and president of Assembly Bio. "In order to realize our mission to bring finite and curative treatments to patients with chronic HBV, we must address the key drivers that contribute to HBV's lifelong persistence in patients. We are encouraged by the data being presented at AASLD, including with our next-generation core inhibitors 3733 and 4334, and we remain confident in our belief that combination strategies centered around core inhibitors and NrtIs will one day contribute to finite, curative therapies and the elimination of HBV."

In the late-breaking poster entitled "*Preclinical characterization of ABI-4334, a novel, highly potent core inhibitor for the treatment of chronic hepatitis B virus infection,"* preclinical data demonstrate that 4334 inhibits pgRNA encapsidation and cccDNA formation with single-digit nanomolar potency against both these mechanisms of action and is also active across all HBV genotypes. Evaluation in preclinical models predicts that a 300 mg dose of 4334 once a day will achieve trough concentration values that are approximately 200-fold greater than the EC_{50} needed to block pgRNA encapsidation and approximately 40-fold greater than the EC_{50} needed to block cccDNA formation. Phase 1 studies with 4334 are planned for 2022.

The poster entitled "*Safety and pharmacokinetics of ABI-H3733, a novel 2nd generation HBV core inhibitor: Results from a Phase 1a study in healthy volunteers,"* includes data from a dose escalation study in 40 healthy volunteers. ABI-H3733, a novel next-generation core inhibitor also designed for increased potency against the formation of cccDNA, was generally well tolerated with no serious adverse events, and all subjects completed the study. Oral liquid formulation doses were administered as single doses of 100 mg, 250 mg, or 500 mg or daily over 5 days at 250 mg. The serum half-life of 3733 was approximately 18 - 24 hours, supporting once daily, oral administration in chronic HBV patients, and plasma concentrations are predicted to exceed *in vitro* protein-adjusted (pa)EC_{50} values for inhibition of HBV DNA replication and cccDNA formation. Importantly, C_{min} projections for a new tablet formulation are approximately 150 and 29 times higher than the paEC_{50} for inhibition of HBV DNA formation and cccDNA formation, respectively. A Phase 1b study evaluating 3733 in patients with chronic HBV infection is planned to start in 2022.

Vebicorvir, the company's lead core inhibitor product candidate, is the focus of an oral presentation entitled " *HBV pgRNA and DNA both rebound immediately following discontinuation of the core inhibitor vebicorvir despite continued NrtI treatment in patients with HBeAg positive chronic hepatitis B virus infection: Findings from a Phase 2 open label study*." The data demonstrate that treatment with VBR in combination with NrtI, of both initially treatment-naïve (TN) and virologically suppressed patients, led to a deeper level of viral suppression as measured by pgRNA and HBV DNA levels. Following VBR discontinuation at the end of the study, and despite continued NrtI therapy, there was an immediate viral rebound observed with an approximately 2 log_{10} increase in pgRNA levels in all patients and a 1 log_{10} increase in HBV DNA levels in TN patients. These results provide additional evidence that VBR in combination with Ntrl leads to deeper virologic suppression and support the additive role of HBV core inhibitors in combination therapies. Throughout the trial, VBR treatment was not associated with viral resistance, and VBR had a favorable safety profile in over 100 patients treated for up to 1.5 years.

AASLD Presentations and Posters
Posters are now available to conference registrants through the online AASLD portal and under the “Events & Presentations” page in the “Investors” section of Assembly Bio's website at www.assemblybio.com. The oral presentation will be available beginning at 10 am ET on November 14.

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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