Assembly Biosciences Presents Final Results of Phase 1b Study of ABI-H0731 at 2018 AASLD

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First Presentation of HBV RNA Reduction Data, a Distinguishing Feature of Core Inhibitors

SAN FRANCISCO, Nov. 12, 2018 (GLOBE NEWSWIRE) -- Assembly Biosciences, Inc. (NASDAQ: ASMB), a clinical-stage biotechnology company developing innovative therapeutics targeting hepatitis B virus (HBV) and diseases associated with the microbiome, presented final data from the Phase 1b study of ABI-H0731 in patients with chronic HBV at the American Association for the Study of Liver Diseases (AASLD) Annual Meeting (The Liver Meeting®), in San Francisco.

"We are excited about our progress with ABI-H0731 and our deep pipeline of core inhibitors," said Uri Lopatin, MD, Chief Medical Officer of Assembly Biosciences. "The HBV RNA data shown in our presentation at AASLD serves as an important marker of the core inhibitor mechanism and distinguishes it from standard of care nucleos(t)ide or 'nuc' therapy. We are currently evaluating ABI-H0731 in two Phase 2a studies and we also recently announced the initiation of our Phase 1a study of ABI-2158 and our selection of a third HBV core inhibitor, ABI-H3733. This progress reflects our commitment to expand our portfolio with potent candidates that have the potential to bring cures to patients in need."

ABI-H0731-101b study was a Phase 1b study designed to test multiple dose levels of ABI-H0731 monotherapy for 28 days in treatment-naïve HBV patients. The primary objectives were to measure the safety, tolerability and pharmacokinetics (PK) of ABI-H0731 in addition to antiviral potency when administered as monotherapy. The Phase 1b patient study enrolled 38 HBeAg positive and negative patients across four dose levels (100, 200, 300 and 400 mg) of ABI-H0731. All cohorts yielded potent antiviral activity, with mean maximal HBV DNA declines of 2.8 $\log_{10}$ IU/mL and maximal declines of up to 4.1 $\log_{10}$ IU/mL at 300 mg once daily dose. RNA declines paralleled DNA declines at all doses with maximal declines of up to 2.6 $\log_{10}$ IU/mL in the HBeAg positive subjects at the 300 mg dose. Reductions in HBV RNA serve as a distinguishing feature of core inhibitor activity and are not observed with standard of care nucleos(t)ide therapy.

Intensive PK evaluation showed ABI-H0731 quickly achieved steady state plasma concentrations, with minimal (less than two fold) accumulation, confirming a once daily dosing schedule. To monitor for resistance, all baseline and end of treatment samples were genotyped and analyzed for both pre-existing and emerging core protein resistance mutations. No patients in the study developed new emerging resistant mutants. There was a single patient with a pre-existing mutation, and this patient still exhibited a 1-log drop in HBV DNA levels.

Across all cohorts in the Phase 1b study, ABI-H0731 was generally safe and well tolerated with no serious adverse events (SAEs) and no dose-limiting toxicities. All treatment emergent adverse events (TEAEs) were observed to be minor (Grade 1), with the exception of an isolated Grade 3 rash at the 400 mg dose that resolved rapidly without intervention other than treatment discontinuation.

Assembly selected the 300 mg once daily dose of ABI-H0731 for the two Phase 2a combination studies that are actively enrolling. The viral antigen proof-of-concept study is enrolling patients actively on 'nuc' therapy who have suppressed viral loads. Patients will continue their 'nuc' therapy and be randomized to either placebo or ABI-H0731 for six months. This study is designed to demonstrate that ABI-H0731 can inhibit the generation of cccDNA molecules by showing a decline in the surrogate markers of cccDNA. A second Phase 2a study is enrolling treatment-naïve HBeAg positive patients and is designed to show superiority of the combination of ABI-H0731 and 'nuc' therapy to monotherapy with 'nuc' alone. This study will evaluate the antiviral effectiveness of combination therapy by comparing the rates of HBV viral load declines between monotherapy and combination therapy over six months. The company anticipates results from these studies during the first half of 2019.

About Assembly Biosciences
Assembly Biosciences, Inc. is a clinical-stage biotechnology company developing innovative therapeutics targeting hepatitis B virus (HBV) and diseases associated with the microbiome. The HBV program is focused on advancing a new class of potent, oral core inhibitors that have the potential to increase cure rates for chronically infected patients. The microbiome program is developing novel oral live synthetic biotherapeutic candidates with Assembly's fully integrated platform, including a robust process for strain identification and selection, GMP banking and production, and targeted delivery to the lower gastrointestinal tract with the GEMICEL® technology. For more information, visit assemblybio.com.

Forward-Looking Statements
The information in this press release contains forward-looking statements regarding future events, including statements about the clinical and therapeutic potential of core inhibitors, including ABI-H0731, ABI-H2158 and ABI-H3733, Assembly's development

programs, the results of clinical trials being predictive of future clinical trials, the initiation, progress and results of Assembly's ongoing and planned clinical studies and the timing of these events. Certain forward-looking statements may be identified by reference to a future period or by use of forward-looking terminology such as "anticipates", "will," and "potential." Assembly 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. Actual results or developments may differ materially from those projected or implied in these forward-looking statements. More information about the risks and uncertainties faced by Assembly are more fully detailed under the heading "Risk Factors" in Assembly's Quarterly Report on Form 10-Q for the quarter ended September 30, 2018 filed with the Securities and Exchange Commission. Except as required by law, Assembly 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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