Assembly Biosciences Presents Positive Interim Data from Phase 1a and 1b Studies of ABI-H0731 in HBV Patients in a Late-Breaker Session at the EASL Conference

April 12, 2018

Robust antiviral activity observed in HBV patients

Generally safe and well tolerated

Planning underway for Phase 2a studies beginning summer 2018

Company to host conference call on Thursday, April 12th at 8am ET / 2pm CEST

INDIANAPOLIS and SAN FRANCISCO, April 12, 2018 (GLOBE NEWSWIRE) -- Assembly Biosciences, Inc. (NASDAQ:ASMB), a clinical-stage biotechnology company advancing a new class of oral therapeutics for the treatment of hepatitis B virus (HBV) infection and novel oral live biotherapeutics for disorders associated with the microbiome, today presented interim results from Phase 1a and 1b study of ABI-H0731, a novel antiviral in development for the treatment of chronic HBV infection, in a "late-breaker" poster presentation at The International Liver Congress™, the Annual Meeting of theEuropean Association for the Study of the Liver (EASL). A copy of the poster can be found at assemblybio.com on the "Events & Presentations" page under "Investors."

"The data presented today from our ongoing Phase 1b monotherapy study for '731 show excellent potency and dose response across patient cohorts as well as a favorable safety profile," said Derek Small, President and Chief Executive Officer. "We are seeing viral load responses in both HBeAg positive patients and HBeAg negative patients that exceed our expectations, and we are planning to move ahead expeditiously with our Phase 2a clinical trial this summer."

The late-breaker poster outlines interim data from the ongoing Phase 1b antiviral efficacy study and a recently completed Phase 1a safety and pharmacokinetic (PK) study of ABI-H0731, a novel, oral Core protein Allosteric Modifier (CpAM), with selective and potent activity against all major HBV genotypes. To date, two cohorts (100 and 200 mg) of HBV patients have completed dosing in the Phase 1b trial, in addition to three (100, 200 and 300 mg) additional cohorts in a Phase 1a study in healthy volunteers. A third HBV patient cohort receiving 300 mg is ongoing, though only initial results are reported. Two HBeAg negative patients have also been treated at 400 mg.

The Phase 1b patient study enrolled both HBeAg positive and negative patients. Potent antiviral activity was observed across patient cohorts in a dose dependent manner. Specifically, in the ongoing 300 mg dose cohort, the mean overall decline from baseline is currently ≥2.8 $\log_{10}$ IU/mL, with ≥2.9 and 2.5 $\log_{10}$ IU/mL mean declines in HBeAg positive and negative patients, respectively. Maximal viral load declines of 3.6 to 4.0 $\log_{10}$ IU/mL were observed in certain HBeAg negative patients treated at all dose levels (100 to 400 mg). The company intends to report complete results from this study at a scientific conference later this year.

Across all cohorts in the Phase 1a and Phase 1b studies, ABI-H0731 was generally safe and well tolerated. No SAEs or dose-limiting toxicities were identified, and there was no pattern of treatment emergent clinical or laboratory abnormalities observed. Among the 62 patients and volunteers treated, 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.

The interim study results support the advancement of ABI-H0731 into Phase 2a combination studies expected to begin this summer. The first study will enroll HBeAg positive patients on standard of care nucleos(t)ide therapy with fully suppressed viral loads. Patients will continue their nucleos(t)ide therapy and be randomized to either placebo or ABI-H0731 for 6 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 will enroll treatment naïve HBeAg positive patients and is designed to compare the antiviral effectiveness of standard of care nucleoside therapy alone compared to standard of care in combination with ABI-H0731 for six months. The company anticipates results from these studies during the first half of 2019.

About the Phase 1a and Phase 1b Studies
ABI-H0731-102 is a Phase 1a study designed to administer multiple dose levels of ABI-H0731 for 14 days to healthy volunteers. The primary objectives are to expand the safety, tolerability and pharmacokinetics database of ABI-H0731. *ABI-H0731-101b* is a Phase 1b study designed to test multiple dose levels of ABI-H0731 for 28 days in treatment naive HBV patients. The primary

objectives are to measure the safety, tolerability and pharmacokinetics of ABI-H0731 in addition to its initial antiviral potency when administered as monotherapy. The Phase 1b study enrolled cohorts composed of both HBeAg positive and HBeAg negative patients at a ratio of 7:5 respectively, with one patient in each group receiving placebo.

Conference Call and Webcast
Assembly intends to host a conference call and live audio webcast on Thursday, April 12, 2018, at 8:00 am ET/ 2:00 pm CEST.

The live audio webcast may be accessed through the "Events & Presentations" page in the "Investors" section of the company's website at assemblybio.com. Alternatively, participants may dial (866) 362-6480 (domestic) or (706) 679-0386 (international) and refer to conference ID 3669097.

The archived webcast will be available on Assembly's website beginning approximately two hours after the event and will be archived and available for replay for at least 30 days after the event.

About Assembly Biosciences
Assembly Biosciences, Inc. is a clinical-stage public biotechnology company developing two innovative platform programs: an HBV program advancing a new class of oral therapeutics for the treatment of hepatitis B virus (HBV) infection and a microbiome program developing novel oral live biotherapeutics designed to address diseases associated with the microbiome. Assembly's HBV program is advancing multiple drug candidates with the aim of increasing cure rates in patients with chronic HBV. The company's microbiome program consists of a fully integrated platform that includes a robust strain identification and selection process, methods for strain isolation and growth under current Good Manufacturing Practices and a patent-pending delivery system, GEMICEL®, which allows for targeted oral delivery of live biologic and conventional therapies to the lower gastrointestinal tract. Assembly is developing a robust pipeline of product candidates in multiple disease indications. 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 ABI-H0731 and Assembly's development programs, interim data's reliability to predict completed clinical study results, the initiation, progress and results of Assembly's ongoing and planned clinical trials, and the timing of these events. Certain forward-looking statements may be identified by reference to a future period or periods or by use of forward-looking terminology such as "plan," "intends," "designed" or "developing." 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 Annual Report on Form 10-K for the year ended December 31, 2017 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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Source: Assembly Biosciences