Assembly Biosciences Announces Completion of Enrollment in Two Phase 2a Studies with ABI-H0731 for Chronic Hepatitis B Virus

January 7, 2019

Interim results anticipated in Q2 of 2019

SAN FRANCISCO, Jan. 07, 2019 (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, today announced completion of patient enrollment in two Phase 2a studies with ABI-H0731, a potent core inhibitor, for the treatment of HBV. The studies are ongoing, and the company anticipates reporting interim results from both studies during Q2 of 2019.

“Completing patient enrollment in both of our first Phase 2 studies marks an important milestone for our ongoing HBV clinical program and brings the potential of a cure closer to the millions of patients suffering from this chronic disease,” said Derek Small, President and Chief Executive Officer. “The data from these studies will serve to inform the timelines of the HBV cure program as well as the design of future registrational studies. We anticipate sharing interim data from the ongoing studies at scientific conferences this year. We want to express our gratitude to all the investigators, caregivers and patients who have dedicated their time and effort to participate in these studies at the many sites open around the world.”

ABI-H0731-201 is a Phase 2a “viral antigen” proof-of-concept study that enrolled HBeAg positive and negative patients whose viral load is already suppressed on active nucleos(t)ide (‘Nuc’) therapy. The enrolled patients continue their ‘Nuc’ therapy and were randomized 3:2 to either placebo or ABI-H0731 for six months. This study is designed to evaluate the effectiveness of ABI-H0731 in inhibiting the generation of new covalently closed circular DNA (cccDNA). Based on previous studies, inhibition of new cccDNA generation while existing cccDNA decays should manifest as a decline in viral antigens HBsAg and HBeAg.

ABI-H0731-202 is a Phase 2a “viral load” study that enrolled treatment-naïve HBeAg positive patients and is designed to evaluate the *de novo* combination of ABI-H0731 and ‘Nuc’ therapy (entecavir) to ‘Nuc’ monotherapy alone. This study is designed to assess the benefit of combination therapy by comparing the relative rates of HBV viral load declines over six months.

At the end of six months, patients from both studies have the opportunity to rollover to an open label combination (ABI-H0731 + Nuc) and continue treatment for up to an additional year. The data generated over the course of the Phase 2a studies will help to inform timelines and registration strategies for this novel class of HBV therapies. The U.S. Food and Drug Administration (FDA) recently issued draft guidance for HBV drug development[1] reviewing development considerations for direct acting antiviral approaches such as Assembly’s core inhibitors.

In addition to ‘731, Assembly continues to advance its deep pipeline of potent HBV core inhibitors with ABI-2158, its second core inhibitor, in an ongoing Phase 1a study in healthy volunteers. Data from this study is expected to be available in the first half of 2019. The company is planning to advance its third core inhibitor, ABI-H3733, into clinical trials in 2019.

[1]U.S. Department of Health and Human Services. Food and Drug Administration. Center for Drug Evaluation and Research (CDER). (2018 November) *Chronic Hepatitis B Infection: Developing Drugs for Treatment. Guidance for Industry*. Washington, DC. https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM624695.pdf

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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