



Assembly Biosciences Initiates Two Phase 2a Trials of ABI-H0731 for the Treatment of Hepatitis B Virus Infection

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Key aim is to demonstrate that core inhibitor therapy combined with standard of care antivirals can offer curative potential for HBV

INDIANAPOLIS and SAN FRANCISCO, July 09, 2018 (GLOBE NEWSWIRE) -- Assembly Biosciences, Inc. (Nasdaq:ASMB), today announced the initiation of two multi-center, randomized, placebo controlled Phase 2a trials of ABI-H0731 for the treatment of patients with chronic HBV infection. ABI-H0731 is Assembly's lead HBV core inhibitor shown to exhibit potent antiviral activity in a Phase 1b trial, the results of which were presented in April at the European Association for the Study of the Liver (EASL) meeting in Paris.

"We are excited to initiate these next clinical studies, which will evaluate ABI-H0731 in combination with standard nucleos(t)ide therapy in patients with chronic HBV infection," said Uri Lopatin, MD, Chief Medical Officer of Assembly Biosciences. "These studies will provide data on the potential of ABI-H0731 to increase cure rates by suppressing viral replication to a greater degree than is currently achieved with standard nucleos(t)ide therapy alone. Such a result would support that clinical cure of chronic HBV may be possible with a finite course of direct acting combination therapy."

"Even with indefinite treatment with the currently available nucleoside and nucleotide inhibitors, we are not able to fully suppress viral replication, which will be necessary for patients to achieve a cure for chronic HBV," said Douglas T. Dieterich, M.D., Director, Institute of Liver Medicine, Professor of Medicine at Mount Sinai, New York, and an investigator on both trials. "Core inhibitors target different parts of the HBV life cycle than the current therapies, and may result in both greater viral suppression and increased loss of cccDNA, which is central to HBV persistence. Combining these new mechanisms of action with existing direct acting antivirals looks promising. I look forward to exploring this further in the trials and seeing the results."

The first Phase 2a trial, ABI-H0731-201 (the "viral antigen trial"), is enrolling HBeAg positive HBV patients whose viral load has already been suppressed on a standard of care nucleos(t)ide therapy. Approximately 45 patients will be randomized 3:2 to receive either daily ABI-H0731 (300 mg) or placebo in addition to their continued nucleos(t)ide therapy for six months. The viral antigen trial will compare declines in HBV S antigen (HBsAg) and HBV E antigen (HBeAg) in subjects on combination therapy to those seen in subjects on monotherapy, as well as the safety and tolerability of ABI-H0731. Blood levels of HBsAg and HBeAg can be biomarkers for the presence of cccDNA in HBV infected liver cells. Accordingly, a decline in these markers would be expected to correlate with inhibition of cccDNA generation.

The second Phase 2a trial, ABI-H0731-202 (the "viral load trial"), is enrolling HBeAg positive HBV patients who are naïve to nucleos(t)ide treatment. Approximately 24 patients will be randomized 1:1 to receive either daily ABI-H0731 (300 mg) or placebo in combination with standard of care entecavir (0.5 mg) for six months. The viral load trial will assess the antiviral potency of the combination compared with entecavir alone. Endpoints include the speed and depth of viral suppression, as well as changes in biomarkers (HBsAg and HBeAg) for the presence of cccDNA, and the safety and tolerability of ABI-H0731.

Initial results from the 201 and 202 trials are anticipated in the first half of 2019. More information on the trials may be found on www.clinicaltrials.gov under the trial identifiers NCT03576066 and NCT03577171.

About Assembly Biosciences

Assembly Biosciences, Inc. is a clinical-stage public biotechnology company developing two innovative platform programs: a Hepatitis B (HBV) program advancing a new class of oral therapeutic candidates for the treatment of HBV infection and a microbiome program developing novel oral live biotherapeutic candidates 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 patented 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 core inhibitors, including ABI-H0731, the timing, size and results of Assembly's planned clinical studies and the timing of reporting clinical trial results. Certain forward-looking statements may be identified by reference to a future period or by use of forward-looking terminology such as "will," "expected," 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 March 31, 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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