Assembly Biosciences Announces FDA Fast Track Designation Granted to ABI-H0731 for the Treatment of Hepatitis B Virus Infection

July 25, 2018

INDIANAPOLIS and SAN FRANCISCO, July 25, 2018 (GLOBE NEWSWIRE) -- Assembly Biosciences, Inc. (NASDAQ:ASMB) today announced that the U.S. Food and Drug Administration (FDA) has granted Fast Track designation to ABI-H0731 for the treatment of patients with chronic Hepatitis B infection. ABI-H0731 is Assembly's lead oral HBV core inhibitor, which is being evaluated in two global Phase 2a proof of concept studies that are currently enrolling patients.

The Fast Track program is intended to facilitate the development and review of drug candidates that treat serious conditions and fill an unmet medical need. A drug candidate with Fast Track designation is eligible for greater access to the FDA for the purpose of expediting the drug product candidate's development, review and potential approval.

"More than one million individuals in the U.S. suffer from chronic Hepatitis B infection, which can progress to cirrhosis and liver cancer, eventually leading to death. Despite existing antiviral therapies, cures are rare, so the need for more effective and potentially curative treatments is tremendous," said Uri Lopatin, MD, Chief Medical Officer of Assembly Biosciences. "We are encouraged that ABI-H0731 was granted Fast Track Designation. This will allow us to work closely with the FDA in our efforts to bring this new therapy to HBV patients as quickly as possible."

Assembly recently initiated two multi-center, randomized, placebo controlled Phase 2a trials of ABI-H0731, which are actively recruiting and dosing subjects at multiple locations in the U.S. and globally. The ABI-H0731-201 "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. Patients will be randomized to receive either daily ABI-H0731 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 and HBV E antigen as well as safety and tolerability of the combination therapy to that of patients on standard-of-care nucleos(t)ide therapy alone. In the ABI-H0731-202 "viral load trial," HBeAg positive HBV patients are being enrolled who are naïve to nucleos(t)ide treatment and will be randomized to receive either daily ABI-H0731 or placebo in combination with entecavir for six months. The viral load trial will assess the antiviral potency as measured by viral DNA suppression as well as safety and tolerability of the combination compared with entecavir alone. Initial results from both studies are anticipated in the first half of 2019.

About Assembly Biosciences
Assembly Biosciences, Inc. is a clinical-stage biotechnology company developing innovative therapeutics targeting Hepatitis B (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, the difficulty of predicting the timing or outcome of FDA reviews, approvals or actions, the timing and results of Assembly's clinical trials 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.

Contacts
Assembly Biosciences, Inc.
Investors:
Lauren Glaser
(415) 521-3828

lglaser@assemblybio.com

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