Assembly Biosciences Initiates Phase 2 Trial Evaluating Second-Generation Core Inhibitor ABI-H2158 for Chronic Hepatitis B Infection

June 25, 2020

SOUTH SAN FRANCISCO, Calif., June 25, 2020 (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 the initiation of a Phase 2 trial of its potent, second-generation core inhibitor, ABI-H2158 (2158). The international multi-center, randomized, placebo-controlled trial will evaluate 2158 with entecavir versus placebo with entecavir in treatment-naïve patients with HBeAg positive chronic hepatitis B infection without cirrhosis.

"We are excited to have three novel core inhibitors advancing in clinical development and to have our more potent second-generation candidate, 2158, now in a Phase 2 proof-of-concept study for chronic hepatitis B infection," said John McHutchison, AO, MD, Chief Executive Officer and President at Assembly Biosciences. "The initial Phase 2 development program with our first-generation core inhibitor, ABI-H0731, has shown us that core inhibitors combined with standard-of-care nucleos(t)ide therapy result in deeper reductions in HBV DNA and pgRNA levels than NrtI alone. The data from this trial with 2158 will further our understanding of the potential for our core inhibitors to drive deeper viral suppression in more patients more rapidly. Our hope is that this suppression will eventually bring patients with chronic hepatitis B infection closer to cure by more potently blocking the generation of new cccDNA, increasing the possibility of achieving sustained virologic response."

In the trial, 80 patients will be randomized three-to-one to receive either 300 mg oral 2158 plus entecavir or placebo plus entecavir once daily for up to 72 weeks. Primary endpoints include change in HBV DNA following 24 weeks of treatment, and safety and tolerability throughout the study. Other endpoints include changes in pgRNA and other viral antigens. Currently, initial sites are open for patient screening, with additional sites planned. Further details may be found at https://clinicaltrials.gov/ using identifier NCT04398134.

This proof-of-concept study builds on results from the recently completed Phase 1b dose-ranging study of 2158, where HBeAg-positive patients received doses of 2158 (100 mg, 300 mg, or 500 mg) or placebo once daily for 14 days. 2158 was well tolerated and demonstrated potent antiviral activity at the 300 mg dose. Clinical data from this trial have been selected as a late-breaker poster at the European Association for the Study of the Liver's (EASL) Digital International Liver Congress, August 27-29, 2020.

About Assembly Biosciences' HBV Core Inhibitor Portfolio
Assembly's HBV portfolio includes three clinical-stage small molecules, all of which are HBV core protein inhibitors that target multiple steps of the HBV life cycle. In Phase 2 clinical trials, first-generation core inhibitor ABI-H0731 administered with nucleos(t)ide analogue reverse transcriptase inhibitor (NrtI) therapy has been well-tolerated, has shown statistically superior antiviral activity in HBV DNA suppression compared to NrtI therapy alone, and has demonstrated significant declines in pgRNA that may indicate decreased cccDNA levels. Assembly's HBV portfolio also includes two potent second-generation candidates, ABI-H2158 in a Phase 2 clinical trial and ABI-H3733 in Phase 1 development.

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 microbial biotherapeutic candidates with Assembly's fully integrated platform, including a robust process for strain identification and selection, GMP manufacturing expertise 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 that are subject to certain risks and uncertainties that could cause actual results to materially differ from those projected or implied. These risks and uncertainties include: Assembly's ability to initiate and complete clinical trials involving ABI-H2158 in the currently anticipated timeframes; safety and efficacy data from ABI-H2158 may not warrant further development; clinical and nonclinical data may not differentiate Assembly's product candidates from other companies' candidates; and other risks identified from time to time in Assembly's reports filed with the U.S. Securities and Exchange Commission (the SEC). All statements other than statements of historical fact are statements that could be deemed forward-looking statements. Readers are cautioned not to rely on these forward-looking statements. 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. More information about the risks and uncertainties faced by Assembly are more fully detailed under the heading "Risk Factors" in Assembly's filings with the Securities and Exchange Commission, including its most recent Annual Report on Form 10-K, Quarterly Reports on Form 10-Q and Current Reports on Form 8-K. Except as required by law, Assembly assumes no obligation to update publicly any forward-looking statements, whether resulting from new information, future events or otherwise.

Contacts
Assembly Biosciences, Inc. Lauren Glaser
Senior Vice President, Investor Relations and Corporate Affairs
(415) 521-3828
lglaser@assemblybio.com

Source: Assembly Biosciences, Inc.