Assembly Biosciences Announces FDA Fast Track Designation Granted to ABI-H2158 for the Treatment of Chronic Hepatitis B Virus Infection

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SOUTH SAN FRANCISCO, Calif., July 09, 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 that the U.S. Food and Drug Administration (FDA) has granted Fast Track designation to ABI-H2158 (2158) for the treatment of patients with chronic HBV infection. 2158 is Assembly's second-generation core inhibitor, which is being evaluated in an ongoing global Phase 2 trial.

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. The Company previously received Fast Track designation for its first-generation core inhibitor ABI-H0731, currently in Phase 2 development.

"We are pleased to have received Fast Track designation for our second-generation core inhibitor 2158 for the treatment of chronic hepatitis B virus infection, a condition that affects over 250 million people worldwide with more than one million infected individuals in the United States," said Luisa Stamm, MD, PhD, Chief Medical Officer at Assembly Biosciences. "This designation holds several important advantages to expedite the development and regulatory review of 2158 and underscores the importance of providing novel treatments to patients."

About Assembly Biosciences' HBV Core Inhibitor Portfolio
Assembly's HBV portfolio includes three clinical-stage small molecules, all of which are HBV core 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.

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