

Assembly Biosciences Announces Presentation at International Association for the Study of the Liver Congress and Update on HBV Program in China

June 21, 2019

SAN FRANCISCO, June 21, 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 that Richard Colonno, PhD, Executive Vice President, Chief Scientific Officer, Virology Operations, will present at the first International Association for the Study of the Liver (IASL) Congress on June 22, 2019 in Beijing.

"We are excited to have the opportunity to highlight our HBV Cure program during the inaugural IASL Congress in Beijing and provide an update on our business activities in China, including drug development efforts in the country. Hepatitis B is considered a major health threat in China, with more than 90 million people living with the infection. It is clear that nucleos(t)ide therapy alone is not capable of completely eliminating viral replication and infection, but the addition of a core inhibitor, like those in Assembly's portfolio, may have the potential to achieve superior antiviral efficacy compared to nucleos(t)ide therapy alone and block cccDNA generation," said Derek Small, President and Chief Executive Officer. "Assembly is also progressing its global regulatory strategy, with two Clinical Trial Applications (CTAs) accepted in China and trial initiations anticipated this year, and its plans to initiate discussions with the U.S. Food and Drug Administration about potential registration pathways."

The oral presentation, "New Therapies to More Effectively Eliminate Viral Replication and Increase Cure Rates in CHB Patients," will review the scientific rationale Assembly is pursuing to improve cure rates in patients with chronic HBV and interim clinical data previously reported by the company in April 2019 at The International Liver Congress™(ILC), the Annual Meeting of the European Association for the Study of the Liver relating to the company's HBV Cure program comprised of clinical candidates ABI-H0731 (731), ABI-H2158 (2158) and ABI-H3733.

The data being reviewed includes the two ongoing Phase 2a studies of 731, Assembly's lead core inhibitor program, in combination with standard of care nucleos(t)ide therapy (Nuc). The studies explore the first two critical steps thought to be necessary for a direct acting antiviral therapy to achieve higher cure rates, including the ability to eliminate residual viremia and the prevention of both new viral replication and new cccDNA generation.

Update Regarding Assembly China

Given the significant impact of chronic HBV infection in China and elsewhere in Asia, Assembly established Assembly Biotechnology Development (Shanghai) Co. Ltd (Assembly China) as a separate wholly owned business unit in 2016 and has made research and clinical development in the region a priority. Assembly China has established focused teams in Beijing and Shanghai to support its clinical trials, regulatory interactions and medical affairs activities. The company has received Clinical Trial Application (CTA) approvals from China's Center for Drug Evaluation (CDE), part of the National Medical Products Administration (NMPA) in China with the plans to initiate clinical trials of both 731 and 2158 at designated leading HBV trial sites in China.

Assembly is collaborating with leading regional experts, including Professor Jinlin Hou, the Director and Professor of the Hepatology Unit and Department of Infectious Diseases, Nanfang Hospital, Southern Medical University, in Guangzhou, China. "HBV infection is reaching epidemic proportions in China and has a devastating impact on patients. New treatment options are needed to eliminate residual viremia and move toward greater rates of cure, so I am pleased to support Assembly's studies exploring the potential of core inhibitors as a key component of more efficacious treatment regimens," said Dr. Hou.

A copy of the IASL presentation will be available on the Events & Presentations page of the Investors section of the company's website at assemblybio.com.

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 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. Certain forward-looking statements may be identified by reference to a future period or by use of forward-looking terminology such as "anticipated," "expected," "intention," "may," "plans," "potential," and "projected." 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. These risks and uncertainties include, among others: the scientific theory for core inhibitors is unproven and novel; top-line or initial data may not accurately reflect the complete results of a particular study or trial; outcomes of clinical studies are uncertain and results of earlier preclinical and nonclinical studies may not be predictive of future clinical studies results. 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, 2019 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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