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Assembly Biosciences Initiates Phase 1 Clinical Program of ABI-H0731 for Treatment of Chronic Hepatitis B Virus Infection

--First of Assembly's Novel Series of HBV Core Protein Allosteric Modulators Enters Clinical Development--

INDIANAPOLIS, Nov. 09, 2016 (GLOBE NEWSWIRE) -- Assembly Biosciences, Inc. (NASDAQ:ASMB), a clinical-stage biotechnology company advancing a new class of oral therapeutics for the treatment of hepatitis B virus (HBV) infection and novel oral biotherapeutics for disorders associated with the microbiome, today announced initiation of a Phase 1a/1b clinical trial of ABI-H0731, its initial Core protein Allosteric Modifier (CpAM) for the treatment of chronic HBV.

The Phase 1a study will assess the safety, tolerability and pharmacokinetics of ABI-H0731 in healthy volunteers. Subsequently, a Phase 1b study will assess the safety, pharmacokinetics and preliminary antiviral efficacy in patients with chronic HBV infection. The company expects to report trial results in the second half of 2017.

"This first clinical study is an important milestone for Assembly," said Uri Lopatin, MD, chief medical officer and vice president of research and development of Assembly Biosciences. "Assembly is committed to developing new oral therapies with curative potential for chronic HBV, a serious disease with low cure rates that afflicts millions of people worldwide. ABI-H0731 is the first clinical candidate to emerge from our CpAM platform, which we believe will prove to be a productive source of compounds designed to attack HBV at multiple points in the viral lifecycle. We expect to initiate additional studies of ABI-H0731 in 2017, as we continue to advance other CpAM candidates towards clinical trials."

Assembly aims to improve on the current low cure rates for chronic HBV by targeting the HBV core protein, an essential viral protein involved in multiple critical functions throughout the HBV lifecycle. Assembly's CpAMs are direct-acting antivirals that allosterically modulate core protein. In preclinical HBV infection assays, Assembly has shown that CpAMs can suppress both viral replication and the cccDNA formation associated with viral persistence.

About Chronic Hepatitis B Virus
HBV afflicts an estimated 240 million people worldwide and is a leading cause of chronic liver disease and liver transplants. An estimated 500,000 to one million people die every year from HBV-related causes. The U.S. Centers for Disease Control reports that almost two million Americans are chronically infected with HBV. There is a great unmet need for more effective therapies for chronic HBV - the current standard of care effectively suppresses but does not cure the condition in the vast majority of patients.

About Assembly Biosciences
Assembly Biosciences, Inc. is a public biotechnology company developing two innovative platform programs: an HBV program advancing a new class of oral therapeutics for the treatment of hepatitis B virus (HBV) infection and a microbiome program developing novel oral biotherapeutics 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 patent-pending delivery system, GEMICEL®, which allows for targeted oral delivery of live biologic and conventional therapies to the lower gastrointestinal tract. The lead program from this platform is in development for the treatment of *C. difficile* infections. Assembly is also developing additional microbiome product candidates. For more information, visit assemblybio.com.

Forward-Looking Statements
The information in this press release contains estimates and other forward-looking statements regarding future events, including statements about the clinical and therapeutic potential of our HBV-cure program, timing of the initiation of and availability of data from our ongoing and planned clinical trials, and plans, strategies, and intentions related to our programs. Certain forward looking statements may be identified by reference to a future period or periods or by use of forward-looking terminology such as "developing," "potential," "projected," "anticipated," "positioned," "strategy," "should" or "may." Such forward-looking statements, which we intend 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, are just predictions and are subject to risks and uncertainties that could cause the actual events or results to differ materially.

These risks and uncertainties include, among others: preclinical models may not be representative of disease behavior in clinical studies; our ability to retain necessary employees and to staff our operations appropriately; the components, timing, cost and results of clinical trials and other development activities involving our product candidates; the unpredictability of the preclinical and clinical development of our product candidates and of the duration and results of regulatory review of those candidates by the FDA and foreign regulatory authorities; our anticipated capital expenditures, our estimates regarding our capital requirements, and our need for future capital; and the possible impairment of, or inability to obtain, intellectual property rights and the costs of obtaining such rights from third parties. These and other potential risks and uncertainties that could cause actual results to differ from the results predicted are more fully detailed under the heading "Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2015, and other reports filed with the Securities and Exchange Commission. It is not possible for Assembly management to predict all risks nor can Assembly assess the impact of all factors on its business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements Assembly may make. In light of these risks, uncertainties and assumptions, the forward-looking events and circumstances discussed in this press release may not occur and actual results could differ materially and adversely from those anticipated. Except as required by law, we assume no obligation to update publicly any forward-looking statements, whether as a result of new information, future events or otherwise.

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