Assembly Biosciences Announces ABI-H0731 Phase 1b Interim Data Accepted as a Late-Breaker Poster at The International Liver Congress™ (EASL)

March 28, 2018

INDIANAPOLIS and SAN FRANCISCO, March 28, 2018 (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 live biotherapeutics for disorders associated with the microbiome, today announced the publication of a late-breaker abstract and planned poster presentation of the Phase 1b clinical trial of ABI-H0731 evaluating safety, tolerability and antiviral activity in subjects with chronic HBV at The International Liver Congress™, the Annual Meeting of the European Association for the Study of the Liver (EASL) being held April 11-15, 2018, in Paris. The abstract includes the preliminary data available from 49 healthy volunteers and patients at the time of submission (February 2018). At EASL, the company intends to present an expanded dataset including three healthy subject cohorts (n=30) and three HBV patient cohorts (n>30) treated with ABI-H0731.

“We are pleased to report that initial results of our ongoing Phase 1b study of ABI-H0731 show an attractive safety profile and significant antiviral potency in both HBeAg positive and negative patients, with viral DNA reductions increasing with increasing dose levels,” said Richard Colonno, PhD, Assembly’s executive vice president and chief scientific officer of virology operations. “An important study objective is to identify the minimal dose that produces maximum efficacy of ABI-H0731. We believe we have identified the dose level sufficient to suppress cccDNA establishment and move forward into Phase 2a proof of concept studies this summer.”

Initial patient data from the ongoing Phase 1b study indicate that ABI-H0731 demonstrates potent antiviral activity with once daily dosing for 28 days, is generally safe and well tolerated, and exhibits increasing plasma exposures with increasing dose. At 100 mg per day, the lowest dose tested, HBV declines of 1.3 and 2.2 $\log_{10}$ IU/mL were observed in HBeAg positive and negative patients (respectively). Declines up to approximately 4 logs in HBeAg negative patients were observed following administration of 400 mg per day. HBV RNA reductions were generally proportional to reductions of plasma HBV DNA. No serious adverse events (AEs) and no dose limiting laboratory toxicities were observed. A single Grade 3 treatment-emergent AE (TEAE) leading to drug discontinuation was seen in one patient at the 400 mg dose, otherwise all TEAEs were mild (Grade 1) and/or unrelated to study drug. Over 60 healthy volunteers and patients have been dosed to date, with no dose limiting side effects.

Poster #LBP-012
Title: Interim safety, tolerability pharmacokinetics, and antiviral activity of ABI-H0731, a novel core protein allosteric modulator, in healthy volunteers, and non-cirrhotic viremic subjects with chronic hepatitis B
Date: Thursday, April 12-14, 2018
Time:9:00 am – 5:00 pm CET

The abstract is expected to be posted in the online congress program: https://ilc-congress.eu

About Assembly Biosciences
Assembly Biosciences, Inc. is a clinical-stage 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 live 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. Assembly is developing a robust pipeline of product candidates in multiple disease indications. For more information, visit www.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 Assembly’s development programs and the timing of clinical trials. Certain forward-looking statements may be identified by reference to a future period or periods or by use of forward-looking terminology such as “progressing,” “designed,” “believe” or “developing.” 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 Annual Report on Form 10-K for the year ended December 31, 2017 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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Source: Assembly Biosciences