Assembly Biosciences Presents Data Highlighting Next-Generation HBV Core Protein Inhibitors at EASL 2019

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Phase 1a study of ABI-H2158 demonstrated safety, tolerability and achievement of target liver concentrations

ABI-H3733 demonstrated enhanced potency in preclinical studies

HBV cccDNA shown to have a limited half-life, suggesting potential for curative treatment regimen

Interim data from Phase 2a studies with lead Core Inhibitor ABI-H0731 to be presented during the late-breaker oral session on Saturday, April 13, 2019; selected among "Best of ILC"

Company to host conference call and webcast on Monday, April 15, 2019 at 8:00am ET to discuss interim Phase 2a results of ABI-H0731

SAN FRANCISCO, April 11, 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, is presenting clinical and preclinical data from its next generation core protein inhibitors (CIs), ABI-H2158 and ABI-H3733, as well as continued research on the turnover rate of cccDNA at The International Liver Congress™ (ILC), the Annual Meeting of the European Association for the Study of the Liver (EASL) in Vienna, Austria. Interim results from the ongoing Phase 2a studies of ABI-H0731 will be presented during the late-breaker oral session on Saturday, April 13, 2019. The presentation was also selected as a "Best of ILC" entry. Assembly will host a conference call and webcast on Monday, April 15, 2019 at 8:00am EDT to discuss the results.

"At Assembly, we are dedicated to increasing cure rates for individuals with chronic HBV. The breadth of data we are presenting at the 2019 ILC highlights our deep pipeline of novel core inhibitor candidates and we are increasingly optimistic about the therapeutic potential of incorporating this new class of antivirals into future treatment regimens," said Richard Colonno, PhD, Executive Vice President and Chief Scientific Officer of Virology Operations at Assembly. "We are pleased that ABI-H2158 was well tolerated in healthy subjects and exhibits pharmacokinetic properties that enable once daily administration. Additionally, the favorable preclinical profile and enhanced potency demonstrated with ABI-H3733 support its continued advancement into the clinic early next year."

Dr. Colonno continued, "Our ongoing research on the kinetics of HBV cccDNA turnover reinforces our earlier findings that cccDNA turnover can occur in months, and not years, as previously thought. These findings suggest that direct-acting oral antiviral regimens, such as a CI in combination with a nucleos(t)ide polymerase inhibitor, may fully suppress viremia, inhibit the establishment of new cccDNA, and ultimately represent a new treatment approach for HBV patients."

ABI-H2158 – Late Breaker Poster Presentation
Phase 1a Study of the Safety, Tolerability and Pharmacokinetics of ABI-H2158, a Novel Second-Generation HBV Core Inhibitor, In Healthy Volunteers
The Phase 1a study of ABI-H2158 (2158), Assembly's novel second generation pan-genotypic core inhibitor, assessed safety, tolerability and pharmacokinetics (PK) in 48 healthy volunteers. 2158 was well tolerated following single and multiple ascending doses. No significant food effect was seen when administered with a standardized high-fat meal. There were no dose dependent treatment-emergent adverse events and no pattern of clinical safety nor laboratory abnormalities observed within or across any cohorts. Importantly, trough liver concentrations are projected to achieve exposures in excess of the *in vitro* EC_{90} 334 nM for cccDNA establishment with once daily administration. A Phase 1b dose-ranging study has been initiated to assess the safety, PK and antiviral efficacy of 2158 in patients with chronic HBV infection.

ABI-H3733 – Oral Presentation
Preclinical Profile of HBV Core Protein Inhibitor, ABI-H3733, a Potent Inhibitor of cccDNA Generation in HBV Infected Cells
ABI-H3733 (3733) is Assembly's third novel core inhibitor derived from a third, distinct chemical scaffold. Its preclinical profile demonstrates potent inhibitory activity against multiple steps in the HBV infection cycle, particularly those relating to cccDNA generation. 3733 possesses promising physical properties, low drug-drug interaction potential and a favorable PK profile in multiple species. Mechanism of action studies suggest enhanced potency in blocking encapsidation of pgRNA and disruption of pre-formed capsids, leading to premature disassembly during trafficking of rcDNA containing capsids to the nucleus during infection. 3733 inhibited cccDNA formation with an EC_{90} of 125 nM. The enhanced potency and favorable preclinical profile support advancement into Phase 1a studies, expected to initiate early next year.

cccDNA Turnover Study– Poster Presentation
Rapid Turnover of HBV cccDNA in Nucleoside-Treated Chronic Hepatitis B Patients During Drug Resistance Emergence and Breakthrough
The current low cure rates for HBV infection on standard of care nucleos(t)ide (Nuc) therapy are believed to be due to an inability to eliminate residual viral replication. As a result, generation of new cccDNA persists despite prolonged therapy. Initial mathematic modeling studies, built on the premise that Nucs effectively blocked new cccDNA formation, estimated that it could take at least 14 years to clear intrahepatic cccDNA from a chronically-infected HBV patient. Using a molecular genetics approach that monitored the emergence and disappearance of Nuc resistance mutations as a genetic marker of cccDNA, Assembly has revisited the question of cccDNA turnover. Evaluations were conducted with patient derived longitudinal liver and serum samples (paired) from two historical clinical studies. In these studies, cccDNA population turnover from sensitive to resistant or from resistant to sensitive occurred in as little as 12-17 weeks, suggesting relatively rapid turnover of cccDNA pools and/or infected cells. This study indicates that existing cccDNA has a limited half-life, suggesting that therapies inhibiting establishment of new cccDNA may lead to higher cure rates for patients with HBV.

ABI-H0731 Phase 2a Interim Results: Oral Late Breaker (Embargoed: "Best of ILC" selection)
Interim Safety and Efficacy Results of the ABI-H0731 Phase 2a Program Exploring the Combination of ABI-H0731 with Nuc Therapy in Treatment-Naïve and Treatment-Suppressed Chronic Hepatitis B Patients

This abstract was selected as an oral late breaker presentation and has been embargoed until Saturday, April 13, 2019 at 7:00am CEST due to its selection as a 'Best of ILC' entry and for the ILC press program. Interim data for the ongoing Phase 2a program evaluating ABI-H0731 in combination with Nucs will be presented at 5:15pm CEST.

Posters and presentations from EASL can be found on the Events & Presentations page in the Investors section of the company's website at assemblybio.com.

Conference Call and Webcast Information
Assembly will host a live conference call and audio webcast on Monday, April 15, 2019 at 8:00am ET to review data presented at EASL. The live audio webcast may be accessed through the Events & Presentations page in the Investors section of the company's website at assemblybio.com. Alternatively, participants may dial (866) 438-0453 (domestic) or (409) 220-9366 (international) and refer to conference ID 8497467. The archived webcast will be available on Assembly's website beginning approximately two hours after the event and will be archived and available for replay for at least 30 days after the event.

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 synthetic 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 and the timing of the initiation of planned clinical trials in our HBV-cure program. Certain forward-looking statements may be identified by reference to a future period or by use of forward-looking terminology such as "expected", "may", "projected" and "potential." 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, 2018 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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