Safety and Antiviral Activity of Assembly Biosciences' First and Second Generation Core Inhibitor Candidates In the Treatment of Chronic Hepatitis B to be Featured in a Late Breaking Session at AASLD

October 16, 2019

- *Phase 2a studies of ABI-H0731 + nucleos(t)ide analogs (Nrtl) in HBeAg+ patients show faster and deeper declines in HBV DNA and RNA with combination than Nrtl alone, as well as subsequent declines in the surrogate markers of cccDNA with long-term treatment*
- *Potent antiviral activity observed in first cohort of HBeAg+ patients treated in 14-day monotherapy study of ABI-H2158*
- *Company to host conference call Monday, November 11, 2019 at 8:30am ET*

SOUTH SAN FRANCISCO, Calif., Oct. 16, 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 data on its lead HBV core inhibitor candidates, ABI-H0731 (731) and ABI-H2158 (2158) for the treatment of chronic HBV will be featured in a late-breaking poster session during the American Association for the Study of Liver Diseases (AASLD) Annual Meeting (The Liver Meeting®), November 8-12, 2019, in Boston.

"We are pleased to have data from our two lead core inhibitor programs featured at the AASLD Annual Meeting, the premier conference in the U.S. for Hepatitis B and other liver diseases, and that our abstracts were selected for late-breaking posters," said John McHutchison, AO, MD, Chief Executive Officer and President. "We are very encouraged that the final Phase 2a data indicate that the addition of 731 to nucleos(t)ide therapy not only produces faster and deeper declines in HBV DNA and pgRNA for patients, but also subsequent declines in the surrogate markers predictive of cccDNA pool depletion. These data combined with a favorable safety and tolerability profile following long-term treatment indicate the potential for our core inhibitor regimens on the path to HBV cure. We continue to advance our clinical portfolio of core inhibitors with interim data from the Phase 1b trial of 2158, our second generation candidate, demonstrating potent antiviral activity as a monotherapy over 14 days of treatment."

ABI-H0731
LP-1
Title: *Continued Therapy with ABI-H0731+Nrtl Results in Sequential Reduction/Loss of HBV DNA, HBV RNA, HBeAg, HBcrAg and HBsAg in HBeAg-Positive Patients*
Session: Late-breaking Poster Session
Location: Hall B
Date: Monday, November 11, 2019
Time: 8:00am ET-5:30pm ET; Poster presentation: 12:30pm ET-1:30pm ET
Presenter: Mark Sulkowski, MD, Medical Director, Viral Hepatitis Center, Johns Hopkins University School of Medicine
Abstract Summary: Final results from Phase 2a are reported for HBeAg+ patients with chronic HBV infection treated with 731+Nrtl for 24 weeks. In Study 202 (Rx naïve patients), greater mean log10 declines in HBV DNA (5.27 vs 3.99; p=0.017) and RNA (2.34 vs 0.61; p<0.001) were achieved with 731+Nrtl (entecavir) versus entecavir alone. In Study 201 (Nrtl-suppressed patients), the proportion of patients on 731+Nrtl versus Nrtl alone achieving DNA target not detected (TND) was 69% vs 0% (p<0.001), and the proportion of patients achieving RNA <35 U/mL whose RNA was ≥35 U/mL at baseline was 52% vs 0% (p=0.0013) respectively. In Study 211, there are 64 HBeAg+ patients currently on extended treatment beyond 24 weeks. Among the 27 HBeAg+ patients receiving 731+Nrtl in Study 201, 41% (11/27) have now achieved DNA TND along with RNA <35 U/mL and HBeAg <1 IU/mL. At their last timepoint, Study 202 patients now in Study 211 (n=22) have demonstrated mean DNA and RNA declines of 6.1 and 3.0 logs, respectively, with observed mean log changes of ≥0.6 for HBeAg (11 patients ≥0.5, 4 patients ≥1.0), >0.8 log for HBcrAg (7 patients ≥1.0, 3 patients ≥2.0) and ≥0.4 log for HBsAg (7 patients ≥0.5, 3 patients ≥1.0). 731 continues to exhibit a favorable safety and tolerability profile in patients treated for up to 1 year, with only mild/moderate adverse events and lab abnormalities, and only a single discontinuation due to a Grade 1 rash. The combination of 731+Nrtl results in faster and deeper declines in HBV DNA and RNA than Nrtl alone, as well as subsequent declines in the surrogate markers of cccDNA (pgRNA, HBeAg and HBcrAg) predictive of cccDNA pool depletion, and HBsAg. The emergent data supports the continued development of 731. Abstract data are as of the time of submission; the poster is expected to include updated safety and efficacy results.

ABI-H2158
LP-14
Title: *The Second-Generation Hepatitis B Virus (HBV) Core Inhibitor (CI) ABI-H2158 is Associated with Potent Antiviral Activity in a 14-Day Monotherapy Study in HBeAg-positive Patients with Chronic Hepatitis B (CHB)*
Session: Late-breaking Poster Session
Location: Hall B
Date: Monday, November 11, 2019
Time: 8:00am-5:30pm ET; Poster presentation: 12:30pm-1:30pm ET
Presenter: MF Yuen, MD, PhD, Chief of Division of Gastroenterology and Hepatology, Queen Mary Hospital, Hong Kong
Abstract Summary: The Phase 1b study is enrolling sequential cohorts of 9 patients and each cohort will be randomized to receive 2158 or placebo (7:2) QD for 14 days in a blinded manner. Dosing in the 1st cohort (100 mg) has been completed. In patients receiving 2158, mean declines from Baseline to Day 15 in HBV DNA and RNA levels were 2.3 $\log_{10}$ IU/mL [range 1.7 – 3.0] and 2.1 $\log_{10}$ IU/mL [range 1.5 - 2.7] respectively. No serious AEs, dose limiting toxicities or premature discontinuations were reported. Three patients reported a total of 5 mild, drug-related AEs that recovered without intervention; dizziness, fatigue, rash, headache and upper abdominal pain. Treatment emergent laboratory abnormalities were infrequent, mild and transient, with no ALT elevations Grade ≥1 in severity. Day 14 plasma 2158 C_{max} and $AUC_{0\text{-}24hr}$ were 3,390 ng/mL and 46,100 hr*ng/mL, respectively. Results from the initial 100 mg low dose of ABI-H2158 cohort demonstrated potent antiviral activity, a favourable safety profile when

administered for 14 days, and support once daily dosing in CHB patients. Abstract data are as of the time of submission; the poster may include data from additional cohorts if available at the time of the conference.

These posters will be made available on the Events & Presentations page in the Investors section of the company's website at assemblybio.com after the scheduled poster session has begun.

Conference Call and Webcast Information
Assembly will host a live conference call and audio webcast on Monday, November 11, 2019, at 8:30 am ET. Details for the conference call will be provided at a later date.

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 and ABI-H2158, the timing of reporting data and the results of clinical studies being predictive of results in future clinical studies. Certain forward-looking statements may be identified by reference to a future period or by use of forward-looking terminology such as "anticipated," "expects," "may" "suggest," "will" 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 Quarterly Report on Form 10-Q for the quarter ended June 30, 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.

Contacts
Assembly Biosciences, Inc.
Investors:
Lauren Glaser
(415) 521-3828
lglaser@assemblybio.com

Source: Assembly Biosciences, Inc.