Assembly Biosciences Presents Data from HBV Core Inhibitor Programs at the International Liver Congress™ EASL 2021

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SOUTH SAN FRANCISCO, Calif., June 23, 2021 (GLOBE NEWSWIRE) -- Assembly Biosciences, Inc. (Nasdaq: ASMB), a clinical-stage biotechnology company developing innovative therapeutics targeting hepatitis B virus (HBV), today announced data from its three clinical-stage core inhibitor programs, vebicorvir (VBR or ABI-H0731), ABI-H2158 (2158), and ABI-H3733 (3733), in an oral presentation and two poster presentations during the International Liver Congress™ 2021, the Annual Meeting of the European Association for the Study of the Liver (EASL), taking place virtually June 23-26, 2021.

“We are pleased that the analyses of our next generation core inhibitors were selected for an oral presentation at EASL. We have demonstrated with VBR, our first-generation candidate, that we can achieve deep virologic suppression when combined with nucleos(t)ide reverse transcriptase inhibitor (NrtI) therapy in patients with chronic hepatitis B, and we now project that 2158 and 3733 will have increased potency and coverage to prevent cccDNA generation based on in vitro potency and clinical pharmacokinetic data. We are also encouraged by the enhanced profile of our fourth core inhibitor, which we plan to nominate by mid-year and has potential to be best-in-class,” said John McHutchison, AO, MD, Chief Executive Officer and President of Assembly Bio. “The further analyses from the Phase 2 studies of VBR in our EASL poster presentations continue to inform our development strategy and the HBV field and will provide us greater insight as we conduct clinical trials combining our core inhibitors with NrtI and additional antiviral mechanisms. Overall, our data to date support our belief that core inhibitors combined with NrtI will form the backbone of finite and curative therapies for patients.”

Assembly Bio’s Next-Generation HBV Core Inhibitors, 2158 and 3733
In an oral presentation, William Delaney, PhD, Chief Scientific Officer, describes data evaluating human plasma and estimated liver concentrations of VBR, 2158, and 3733 in relation to their respective protein-adjusted EC_{50} values in primary human hepatocytes. The intent of the analysis was to assess antiviral activity (assembly and release of new viral particles) and prevention of formation of new cccDNA of each of the three candidates. To date, core inhibitors have been inherently more potent against the formation of new virions (antiviral activity). Consequently, the company’s strategy is to optimize these next-generation candidates for greater potency against the generation of new cccDNA and employ both activities in combination regimens for maximal impact in patients. Plasma C_{min} values for VBR, 2158, and 3733 are significantly above protein-adjusted EC_{50} values for antiviral activity, and plasma C_{min} values of 2158 and 3733 are significantly above protein-adjusted EC_{50} values for cccDNA prevention. Concentrations for VBR, 2158, and 3733 are predicted to be enhanced in the liver by 18-fold, 5-fold, and 6-fold, respectively.

Assembly Bio’s Lead Core Inhibitor, Vebicorvir
VBR is featured in two poster presentations during EASL, describing the efficacy, safety and resistance profile of virologically-suppressed patients with chronic HBV infection enrolled in the Phase 2 Studies 201 and Study 211 of VBR in combination with NrtI who discontinued treatment.

- Edward Gane, MBChB, MD, FRACP, MNZM, New Zealand Liver Transplant Unit at Auckland City Hospital in New Zealand, reported that combination therapy with VBR and NrtI for an extended period was well-tolerated and resulted in deep virologic suppression, but did not result in sustained virologic response in any patient who met prospective treatment stopping criteria. Post hoc analyses suggest HBcrAg level may be an important component when establishing stopping criteria for future trials.
    - Patients were categorized as having lower or higher off-treatment viral load to enable a univariate logistic regression analysis to evaluate predictive factors.
    - For HBeAg negative patients, entecavir use and HBcrAg<1.5 kU/mL at end of therapy were significant predictors of off-treatment lower viral load. For HBeAg positive patients, age less than 45 years was a significant predictor.
    - Discontinuation of VBR+NrtI was well tolerated with limited adverse events and ALT elevations post-NrtI restart.

- Man-Fung Yuen, MD, PhD, Chief of Division of Gastroenterology and Hepatology at the Queen Mary Hospital in Hong Kong, described a post hoc analysis to investigate whether treatment-emergent core inhibitor substitutions were observed following discontinuation of VBR and NrtI. Sanger sequencing of HBV core and pol/RT was performed on HBV RNA for baseline samples and on HBV DNA for the first two consecutive off-treatment visits with HBV DNA >20 IU/mL. In vitro phenotyping assays were conducted for all novel substitutions observed in the core inhibitor binding pocket. The majority of patients had no core inhibitor substitutions and those that were observed had minimal impact on the in vitro antiviral activity of VBR. There was no emergence or enrichment of core substitutions observed in any patient. For patients who restarted NrtI, the presence of core inhibitor substitutions did not impact HBV DNA resuppression, nor did it impact the

level of viremia off treatment.

Subsequent to the presentations at EASL, Assembly Bio intends to make the oral presentation and posters available on the "Events & Presentations" page in the "Investors" section of its website at www.assemblybio.com.

About HBV
Chronic hepatitis B virus (HBV) infection is a debilitating disease of the liver that afflicts approximately 270 million people worldwide with up to 90 million people in China, as estimated by the World Health Organization. HBV is a global epidemic that affects more people than hepatitis C virus (HCV) and HIV infection combined—with a higher morbidity and mortality rate. HBV is a leading cause of chronic liver disease and need for liver transplantation, and up to one million people worldwide die every year from HBV-related causes.

The current standard of care for patients with chronic HBV infection is life-long suppressive treatment with medications that reduce, but do not eliminate, the virus, resulting in very low cure rates. There is a significant unmet need for new therapies to treat HBV.

About Assembly Biosciences
Assembly Bio is a clinical-stage biotechnology company committed to bringing finite and curative therapies to the 270 million people living with hepatitis B virus (HBV) worldwide. A pioneer in the development of a new class of potent, oral core inhibitor drug candidates, Assembly Bio's approach aims to break the complex viral replication cycle of HBV to free patients from a lifetime of therapy. Assembly Bio's strategy toward cure includes a leading portfolio of more potent, next-generation core inhibitors, proof-of-concept combination studies and a research program focused on the discovery of novel HBV targets. For more information, visit assemblybio.com.

Forward-Looking Statements
The information in this press release contains forward-looking statements that are subject to certain risks and uncertainties that could cause actual results to materially differ. These risks and uncertainties include: Assembly Bio's ability to initiate and complete clinical studies involving its therapeutic product candidates, including studies contemplated by Assembly Bio's clinical collaboration agreements, in the currently anticipated timeframes; safety and efficacy data from clinical studies may not warrant further development of Assembly Bio's product candidates; clinical and nonclinical data presented at conferences may not differentiate Assembly Bio's product candidates from other companies' candidates; continued development and commercialization of Assembly Bio's product candidates, if successful, in the China territory will be dependent on, and subject to, Assembly Bio's collaboration agreement governing its activity in the China territory; Assembly Bio's ability to maintain financial resources necessary to continue its clinical studies and fund business operations; any impact that the COVID-19 pandemic may have on Assembly Bio's business and operations, including initiation and continuation of its clinical studies or timing of discussions with regulatory authorities; and other risks identified from time to time in Assembly Bio's reports filed with the U.S. Securities and Exchange Commission (the SEC). You are urged to consider statements that include the words may, will, would, could, should, might, believes, hopes, estimates, projects, potential, expects, plans, anticipates, intends, continues, forecast, designed, goal or the negative of those words or other comparable words to be uncertain and forward-looking. Assembly Bio 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. More information about Assembly Bio's risks and uncertainties are more fully detailed under the heading "Risk Factors" in Assembly Bio's filings with the SEC, including its most recent Annual Report on Form 10-K, Quarterly Reports on Form 10-Q and Current Reports on Form 8-K. Except as required by law, Assembly Bio 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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