Assembly Biosciences Presents Data from HBV Core Inhibitor Programs in Poster Sessions at the 2020 AASLD The Liver Meeting Digital Experience™

November 13, 2020

- Data show longer-term, differentiated safety profile of vebicorvir and the importance of HBV pregenomic (pg) RNA as a key biomarker, as well as highlight Assembly Bio's core inhibitor clinical pipeline -

SOUTH SAN FRANCISCO, Calif., Nov. 13, 2020 (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 from its HBV core inhibitor programs and related research will be highlighted during four poster sessions – including two late-breakers – at the 2020 American Association for the Study of Liver Diseases (AASLD) The Liver Meeting Digital Experience™. The posters include data from the company's HBV core inhibitor research and development programs, as well as a collaborative translational study using Assembly Bio's sensitive HBV nucleic acid assays.

"Findings from these studies are adding to a growing body of clinical data that supports the differentiated safety profile of vebicorvir in combination with nucleos(t)ide therapy," said Ira M. Jacobson, MD, Director of Hepatology at New York University Langone Medical Center. "New treatment options for HBV patients are long overdue and the addition of a core inhibitor to the standard-of-care regimen may offer better chronic suppressive therapy to a significant patient population. These longer-term safety data, along with the demonstrated association of HBV pgRNA and changes in HBV viral antigens presented at this conference, are very encouraging and support the continued advancement of the company's core inhibitor programs."

"Chronic hepatitis B virus infection is incredibly complex. Through this research, we are proud to continue to contribute to the scientific community's understanding of hepatitis B and the importance of deepening virologic suppression as it relates to both improving chronic suppressive therapy and reducing downstream clinically important liver-related events," said John McHutchison, AO, MD, Chief Executive Officer and President at Assembly Biosciences. "Further, these data highlight the potential of our more potent core inhibitor candidates, ABI-H2158 and ABI-H3733. We believe that core inhibitors represent a significant advancement in the HBV field and we remain focused on upcoming milestones, including planned Phase 3 registrational trials of vebicorvir in China and globally in the first half of 2021."

The Liver Meeting Digital Experience 2020 Presentations:
The posters will be made available on the "Events and Presentations" page in the Investors section of assemblybio.com.

Vebicorvir (VBR, or ABI-H0731), Assembly Bio's Lead HBV Core Inhibitor
Poster Presentation 820: Analysis of the longer-term safety profile of the hepatitis B virus core inhibitor VBR in an open-label extension study
Presenter: Ira M. Jacobson, MD, Director, Hepatology, NYU Langone Health

This poster includes data from a controlled comparison of 24 patients receiving placebo + nucleos(t)ide analogs (NrtI) for 24 weeks versus 95 patients receiving Assembly Bio's lead core inhibitor product VBR + NrtI for up to 1.5 years. Data support the differentiated safety profile and continued development of VBR combination therapy.

Key Results:

- The safety profile of combination treatment with VBR+NrtI was similar to placebo+NrtI over a 24-week controlled-comparison and was stable with longer-term treatment of VBR+NrtI up to 1.5 years.
- Rashes without systemic involvement observed with VBR+NrtI treatment were predominantly Grade 1 resolving without VBR+NrtI interruption.
- There was no pattern of increased alamine aminotransferase (ALT) and/or aspartate aminotransferase (AST), indicative of hepatoxicity.

Late-Breaking Poster LP37: Changes in viral antigens are more strongly associated with HBV pgRNA than HBV DNA in studies of vebicorvir and NrtI in treatment-naive patients with chronic HBV infection
Presenter: Mark Sulkowski, MD, Medical Director, Viral Hepatitis Center, Johns Hopkins University School of Medicine

This poster details the results of post hoc analyses of data from studies of VBR in treatment naïve patients with HBeAg positive chronic HBV infection to better understand the correlations between changes in HBV DNA and pgRNA with those of other HBV antigens. Two approaches were used: correlation analyses with a Pearson's coefficient and a Mixed-Effects Model for Repeated

Measures. These results demonstrate the importance of pgRNA as a meaningful biomarker for chronic HBV.

Key Results:

- Changes in other HBV antigens are more strongly associated with the change in pgRNA compared with the change in HBV DNA.
- Correlations between pgRNA and HBeAg and HBcrAg were greater relative to the correlations with HBsAg, likely due to the substantial contribution of HBV integrants to HBsAg levels.
- A >2 $\log_{10}$ decline in pgRNA in patients receiving VBR + entecavir (ETV) more significantly predicted the decline in the HBeAg and HBcrAg consistent with the second phase decline with core inhibitor treatment reflecting reduction in cccDNA pools.

Assembly Bio's Next-Generation of Core Inhibitors
Late-Breaking Poster LP45: Amino acid substitutions in the inhibitor binding pocket of HBV core protein confer differential changes in susceptibility to three generations of HBV core inhibitors
Presenter: Dawei Cai, PhD, Senior Scientist, Assembly Bio

This poster describes the *in vitro* resistance profiles of Assembly Bio's first-generation core inhibitor, VBR, and next-generation core inhibitor candidates ABI-H2158 (2158) and ABI-H3733 (3733). Researchers evaluated the antiviral activity of these candidates against known substitutions to the core inhibitor binding pocket. They also assessed whether these substitutions affect the ability of core inhibitors to block cccDNA formation as well as HBV replication through inhibition of pgRNA encapsidation.

Key Results:

- 2158 and 3733 showed greater potency in terms of preventing cccDNA formation compared with VBR and had more favorable resistance profiles against a panel of substitutions.
- ETV retains activity against all tested core protein substitutions suggesting that combination therapy with NrtIs will prevent viral breakthrough due to pre-existence or potential emergence of core protein substitutions, consistent with the current clinical data.

Use of Assembly Bio's Highly Sensitive HBV Assays to Characterize the Association of HBV with HCC
Poster 738: Persistently detectable serum HBV pgRNA is associated with subsequent HCC development in chronic hepatitis B patients receiving chronic NrtI treatment
Presenter: Lung-Yi Mak, MBBS, MRCP, PDipID, FHKCP, FHKAM Department of Medicine, Queen Mary Hospital, The University of Hong Kong, Hong Kong

In this poster, researchers detail findings from a case control study to assess whether residual HBV viraemia is associated with the development of hepatocellular carcinoma (HCC), the most common type of primary liver cancer. The study evaluated 104 chronic HBV patients, 39% of whom had cirrhosis, on ≥ 3 years ETV with unquantifiable HBV DNA by standard assays. Findings highlight the need for more potent viral suppression to further reduce the risk of HCC.

Key Results:

- More sensitive assays revealed that patients still had ongoing replication as evidenced by detection of HBV DNA and pgRNA.
- More than 50% of chronic HBV patients on ETV with HBV DNA<LLOQ (lower limit of quantification) by standard assay had persistent viraemia as determined by a more sensitive HBV DNA assay.
- Detectable viral nucleic acids (HBV DNA and/or pgRNA) were associated with a higher 2-year risk of HCC development.

About HBV
Chronic hepatitis B virus (HBV) infection is a debilitating disease of the liver that afflicts over 250 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 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 improve the treatment options available to 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 manufacturing expertise 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 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 trials involving its HBV therapeutic product candidates 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; Assembly Bio may not observe sustained virologic response in patients who stop therapy in Study 211; Assembly Bio's ability to maintain financial resources necessary to continue its clinical trials and fund business operations; any impact that the spread of the coronavirus and resulting COVID-19 pandemic may have on Assembly Bio's business and operations, including initiation and continuation of its clinical trials 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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