Assembly Biosciences Presents New Data Highlighting Entry Inhibitor and Core Inhibitor Programs at EASL's International Liver Congress™ 2023

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SOUTH SAN FRANCISCO, Calif., June 21, 2023 (GLOBE NEWSWIRE) -- Assembly Biosciences, Inc. (Nasdaq: ASMB), a biotechnology company developing innovative antiviral therapeutics targeting serious viral diseases, today announced data from its hepatitis D virus (HDV) and hepatitis B virus (HBV) antiviral pipeline featured in five poster presentations at the International Liver Congress™, the Annual Meeting of the European Association for the Study of the Liver (EASL) taking place in Vienna, Austria, on June 21-24, 2023, including one selected for inclusion in the Best of EASL Congress summary.

"We are excited to share the latest data on our promising HDV/HBV entry inhibitor program and next-generation HBV core inhibitors with the scientific community," said William Delaney, PhD, chief scientific officer of Assembly Bio. "Data presented from our entry inhibitor program, from which we expect to nominate a development candidate this year, highlight our rapid progress in developing a small molecule inhibitor of this validated mechanism. Additionally, we're pleased to share results from our recent clinical studies of 4334 and 3733, which reinforce the ability of these highly potent, next-generation core inhibitors to lead to deep reductions in viral replication and the potential to increase functional cure rates for HBV as part of a combination regimen."

HBV/HDV Entry Inhibitor Program

HDV is a satellite virus only found in the presence of HBV, and HDV/HBV co-infection is considered the most severe form of chronic viral hepatitis due to faster liver disease progression. A poster entitled "*A novel class of orally available small molecules potently inhibit hepatitis B and D virus entry*" presents insights on the identification of a novel class of highly potent, orally bioavailable HBV/HDV entry inhibitors which show nanomolar (nM) potency, metabolic stability and good oral bioavailability. These inhibitors interfere with preS1 protein binding and NTCP-mediated bile acid uptake, reinforcing that the molecular target is NTCP (sodium taurocholate co-transporting polypeptide, a protein exclusively expressed on the membrane of hepatocytes). Assembly Bio anticipates the nomination of a development candidate this year.

Next-Generation HBV Core Inhibitor Candidates ABI-H3733 and ABI-4334

ABI-H3733 (3733) and ABI-4334 (4334) are novel, structurally distinct, orally bioavailable investigational core inhibitors that exhibit nM potency against pgRNA encapsidation and covalently closed circular (ccc)DNA formation.

The poster entitled "*The safety and pharmacokinetics of ABI-4334, a novel next-generation HBV core inhibitor: interim results from a Phase 1 study in healthy volunteers*" showcases data from a single (SAD) and multiple ascending dose (MAD) first-in-human study in healthy volunteers. The therapy was well tolerated when administered orally up to 400 mg as a single dose or up to 200 mg once a day for eight days, with no Grade 3 or 4 adverse events (AEs), serious AEs or deaths. Potential for best-in-class activity is projected, with a once daily dose of 200 mg estimated to achieve 175× the predicted plasma adjusted (pa) EC_{50} values for viral replication inhibition and 34× $paEC_{50}$ for the prevention of cccDNA formation.

The poster entitled "*Safety, pharmacokinetics, and antiviral activity of the next-generation hepatitis B core inhibitor ABI-H3733 in patients with hepatitis B e antigen negative chronic hepatitis B infection: preliminary results from a randomized, blinded, Phase 1b study*" has been selected for inclusion in the viral hepatitis track hub and to be featured in the Best of EASL Congress summary. This poster features Phase 1b study data in which up to 100 mg of 3733 administered daily was shown to be well tolerated over a 28-day period in patients with chronic HBV (cHBV). 3733 showed increased potency compared to data from studies with first-generation core inhibitors as evidenced by rapid, multi-log declines in HBV DNA at low doses and greater proportions of patients achieving HBV DNA 'not detected' by the end of treatment. All patients in the highest dose group achieved HBV DNA below the lower limit of quantification by the end of treatment. All AEs and lab abnormalities were Grade 2 or lower, with no serious AEs, treatment discontinuations or deaths. The pharmacokinetic profile and antiviral activity of 3733 reflect the improved potency of next-generation core inhibitors against both mechanisms of action and potential to advance finite treatment regimens for patients with cHBV.

In vitro data presented in the poster entitled "*Next generation core inhibitors ABI-H3733 and ABI-4334 have significantly improved potency and target coverage for both antiviral and cccDNA formation activities compared to first-generation core inhibitors"* show that 3733 and 4334 are significantly more potent in preventing viral replication and cccDNA formation compared to the first-generation core inhibitor, vebicorvir (VBR). Additionally, these data show that 3733 and 4334 have significantly improved human exposure coverage for both viral replication and cccDNA formation as compared with VBR.

Vebicorvir (VBR) Phase 2 Combination Data

The first-generation core inhibitor candidate, VBR, was evaluated in a Phase 2 study in combination with entecavir (ETV) and pegylated interferon alpha (Peg-IFNα) in patients with hepatitis B e antigen positive cHBV infection. Highlighted in a poster entitled "*Vebicorvir, entecavir, and pegylated interferon in patients with hepatitis B e antigen positive chronic hepatitis B virus infection: findings from a Phase 2, randomized open-label study in China,*" the data suggest that the addition of Peg-IFNα to VBR and ETV does not result in significantly greater declines in HBV parameters compared to the dual agent control arms and is unlikely to result in significant rates of functional cure following 24 weeks of treatment. In the study, the all oral VBR+ETV arm performed similarly to the two Peg-IFNα-containing arms with 6.0 $\log_{10}$ IU/mL and 0.6 $\log_{10}$ IU/mL reductions in HBV DNA and HBsAg from baseline, respectively. VBR+ETV demonstrated a favorable safety profile relative to the Peg-IFNα containing regimens.

Subsequent to presentation at EASL's International Liver Congress™ 2023, Assembly Bio intends to make the posters available on the "Events & Presentations" page in the "Investors" section of its website at www.assemblybio.com.

About Assembly Biosciences
Assembly Biosciences is a biotechnology company dedicated to the development of innovative small molecule antiviral therapeutics designed to change the path of serious viral diseases and improve the lives of patients worldwide. Led by an accomplished team of leaders in virologic drug development, Assembly Bio is committed to improving outcomes for patients struggling with the serious, chronic impacts of herpesvirus, hepatitis B virus (HBV) and hepatitis delta virus (HDV) infections. 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 maintain financial resources necessary to continue its clinical studies and fund business operations; Assembly Bio's ability to initiate and complete clinical studies involving its therapeutic product candidates, including studies contemplated by Assembly Bio's collaboration agreements, in the currently anticipated timeframes; safety and efficacy data from clinical or nonclinical 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; results of nonclinical studies may not be representative of disease behavior in a clinical setting and may not be predictive of the outcomes of clinical studies; 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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