Assembly Biosciences to Highlight Pipeline Progress in HBV and HDV at the 2023 International HBV Meeting

September 19, 2023

-- Two oral presentations and one poster will feature new data from the Company's hepatitis B/hepatitis D entry inhibitor, capsid assembly modulator ABI-4334, and interferon-alpha receptor agonist programs --

SOUTH SAN FRANCISCO, Calif., Sept. 19, 2023 (GLOBE NEWSWIRE) -- Assembly Biosciences, Inc. (Nasdaq: ASMB), a biotechnology company developing innovative antiviral therapeutics targeting serious viral diseases, today announced that the company will present new preclinical data from multiple hepatitis B virus (HBV) and hepatitis D virus (HDV) pipeline programs at the 2023 International HBV Meeting taking place in Kobe, Japan, September 19-23, 2023.

At the meeting, one oral presentation will highlight progress in the company's HBV/HDV oral entry inhibitor program including activity, selectivity and pharmacokinetic (PK) data that support advancement towards development candidate nomination. A second oral presentation reports new data for ABI-4334 (4334), Assembly Bio's most potent capsid assembly modulator (CAM) with a potential best-in-class profile, describing the prevention of HBV DNA integration *in vitro*. The poster presentation, from the company's interferon-α receptor (IFNAR) agonist program, characterizes small molecule IFNAR agonists that closely mimic interferon-α's signaling.

"The data we are presenting at the 2023 International HBV Meeting highlight the exciting progress of our preclinical HBV/HDV entry and IFNAR agonist programs, and we anticipate nominating a development candidate from the HBV/HDV entry inhibitor program this year," said William Delaney, PhD, chief scientific officer of Assembly Bio. "Further, the data reported for 4334 support its potential to prevent HBV DNA integration, a process that has been linked to substantial genetic damage and the development of liver cancer in HBV patients. HBV DNA integration is a pathogenic process that is not directly addressed by nucleos(t)ide analogs and further supports the rationale of targeting the viral core protein through a new class of inhibitors."

HBV/HDV Entry Inhibitor Program

HDV is a satellite virus only found in the presence of HBV infection and is considered the most severe form of viral hepatitis. In an oral presentation entitled *"Pre-clinical profiling of a novel class of orally bioavailable small molecules potently inhibiting hepatitis B and D virus entry,"* the company will present data on a novel class of highly potent, orally bioavailable HBV/HDV entry small molecule inhibitors with favorable drug-like properties. One compound selected for further characterization exhibited potent activity against multiple HBV and HDV genotypes and selective inhibition of sodium taurocholate co-transporting polypeptide (NTCP) compared to other bile acid transporters. This compound further exhibited a favorable PK/pharmacodynamic preclinical profile supporting the potential for once daily dosing. Assembly Bio anticipates nominating a clinical development candidate from the HBV/HDV entry inhibitor program in 2023.

Next-Generation HBV CAM Candidate ABI-4334

4334, which has completed Phase 1a evaluation, is a novel, orally bioavailable investigational next-generation CAM that exhibits nanomolar (nM) potency against pgRNA encapsidation and covalently closed circular (ccc)DNA formation *in vitro*. In patients with chronic HBV infection, HBV DNA integration has been linked to the development of liver cancer. In the oral presentation entitled *"ABI-4334, a novel inhibitor of hepatitis B virus core protein, disrupts DL-DNA containing capsids and prevents HBV DNA integration,"* data show that *in vitro* 4334 disrupts RC (relaxed circular)- and DL (duplex linear)-DNA capsid formation at nM levels and inhibits HBV DNA integration in a dose-proportional manner as shown by inverse PCR and next-generation sequencing analyses. Based on the Phase 1a PK data, the target plasma levels of 4334 required for inhibition of HBV DNA integration in these models are achievable.

Interferon-α Receptor Agonist

Assembly Bio's IFNAR agonist program seeks to engage IFNα signaling using an orally bioavailable liver-focused small molecule approach to improve tolerability. The poster entitled "*Pre-clinical characterization of novel liver-focused small molecules efficiently inhibiting hepatitis B virus by activating type I interferon signaling,*" features preclinical data on a novel class of IFNAR agonists that inhibit HBV infection and replication. *In vivo* analysis of a compound from the series demonstrates that it closely mimics IFNα activity as measured by activating IFN-stimulated response element signaling and inducing the JAK-STAT pathway in the liver and PBMCs. PK data from the same compound exhibit desirable liver exposure and favorable oral bioavailability. Lead optimization of multiple IFNAR agonists is ongoing.

Time and location of the presentations are as follows:

HBV/HDV Entry Inhibitor:

- **Oral Presentation:** Pre-clinical profiling of a novel class of orally bioavailable small molecules potently inhibiting hepatitis B and D virus entry
  Presenter: Marc P. Windisch, PhD, Assembly Bio
  Session: Session IV: Drug discovery in preclinical models
  Date and Time: September 20, 3:30-5:15 PM JST

ABI-4334:

- **Oral Presentation:** ABI-4334, a novel inhibitor of hepatitis B virus core protein, disrupts DL-DNA containing capsids and prevents HBV DNA integration
  Presenter: Nuruddin Unchwaniwala, PhD, Assembly Bio
  Session: Session VIIII: Integration, pathogenesis, and HCC
  Date and Time: September 22, 11 AM-1 PM JST

Interferon-α Receptor Agonist:

- **Poster Presentation:** Pre-clinical characterization of novel liver-focused small molecules efficiently inhibiting hepatitis B virus by activating type I interferon signaling
  Presenter: Marc P. Windisch, PhD, Assembly Bio
  Session: Session IV: Drug discovery in preclinical models
  Date and Time: September 20, 5:15-7:15 PM JST

Assembly Bio intends to make the presentations 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.

Contacts

Investor and Corporate:
Shannon Ryan
SVP, Investor Relations, Corporate Affairs and Alliance Management
(415) 738-2992

sryan@assemblybio.com

Media:
Sam Brown Inc.
Hannah Hurdle
(805) 338-4752
ASMBMedia@sambrown.com