Assembly Biosciences Nominates First Herpesvirus Development Candidate ABI-5366, a Long-Acting HSV-2 Helicase Inhibitor Targeting High-Recurrence Genital Herpes

February 15, 2023

−ABI-5366 Demonstrates Favorable Profile for a Long-Acting Therapeutic in Preclinical Studies

−IND-Enabling Studies Initiating for 5366, Supporting Anticipated IND/CTA Filing in 1H2024

SOUTH SAN FRANCISCO, Calif., Feb. 15, 2023 (GLOBE NEWSWIRE) -- Assembly Biosciences, Inc. (Nasdaq: ASMB), a clinical-stage biotechnology company developing innovative antiviral therapeutics targeting serious viral diseases, today announced the selection of development candidate ABI-5366 (5366) to progress to IND-enabling studies for its long-acting herpes simplex virus type 2 (HSV-2) helicase inhibitor program. 5366 is the first development candidate from Assembly Bio's discovery pipeline nominated for advancement to clinical development since the company announced its expanded research focus outside of hepatitis B last year.

"We're excited to bring forward this novel development candidate from our HSV-2 program targeting high-recurrence genital herpes, a serious chronic viral disease with profound physical and psychological impacts on patients. There has not been a new medicine approved for patients suffering from high-recurrence genital herpes in decades and current therapies are only partially effective in preventing frequent outbreaks," said William Delaney, PhD, chief scientific officer of Assembly Bio.

Assembly Bio's HSV-2 program targets the viral helicase-primase, an essential viral enzyme complex and a clinically validated target. Helicase inhibition has demonstrated greater reductions in HSV-2 shedding, lesions and pain compared to approved suppressive nucleoside analog regimens in previous clinical studies. 5366, a small molecule helicase inhibitor with nanomolar potency *in vitro,* is designed for long-acting administration and has shown favorable pharmacokinetics (PK) for a long-acting therapeutic, including the key property of exceptionally low clearance, in preclinical studies. 5366's preclinical profile shows the potential for at least monthly dosing, and Assembly Bio will continue to evaluate longer dosing intervals as development and formulation progress.

"Assembly Bio's differentiated long-acting approach for HSV-2 offers the potential to maintain optimal drug plasma concentrations over long periods of time. We anticipate this drug profile, supported by 5366's remarkably low clearance, will enhance both adherence and antiviral activity, leading to better outcomes for patients compared to current suppressive regimens that require daily dosing," continued Dr. Delaney. "We are excited to continue advancing this promising candidate quickly toward the clinic and sharing more data on 5366 at scientific conferences in 2023."

About High-Recurrence Genital Herpes

High-recurrence genital herpes associated with HSV-2 infection is characterized by frequent recurrences of lesions (six or more per year) and is estimated to affect up to 40% of HSV-2 genital herpes patients following their first outbreak. Approved suppressive therapy regimens consist of oral daily dosing of nucleoside analogs, a class first approved for genital herpes almost three decades ago, with no new drug approvals in the last 20 years. These suppressive regimens have been shown to reduce the recurrence of genital herpes among patients with high HSV-2 recurrence, but eliminate recurrences for only a minority of these patients.

About Assembly Biosciences

Assembly Biosciences is a clinical-stage biotechnology company dedicated to the development of innovative small molecule antiviral therapeutics with the potential to change the path of serious viral diseases and improve the lives of patients worldwide. The company's hepatitis B virus (HBV) pipeline includes two potent, next-generation HBV core inhibitors in clinical development, which are designed to disrupt the virus' replication cycle at several key points with the aim of achieving finite treatment and functional cures. Assembly Bio's HBV and hepatitis delta virus (HDV) pipeline also includes two complementary approaches, a viral entry inhibitor and an oral, liver-focused, interferon-alpha receptor agonist, with potential application for both HBV and as chronic suppressive therapy for HDV, which is associated with significantly increased disease burden for HBV/HDV patients. The herpesvirus pipeline addresses two serious consequences associated with herpesvirus infections, high-recurrence genital herpes and transplant-associated herpesviruses. 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 HBV, HDV and herpesvirus 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 successfully execute its previously announced reprioritization and restructuring activities, including the CEO transition; potential adverse legal, reputational, operational and financial effects on Assembly Bio resulting from the reprioritization and restructuring activities; 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 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; continued development and commercialization of ABI-H3733, if successful, in the China territory will be dependent on, and subject to, Assembly Bio's collaboration agreement governing this 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, enrollment 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.

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