Antios Therapeutics and Assembly Biosciences Announce Clinical Collaboration Agreement to Evaluate the Combination of ATI-2173 and Vebicorvir in Patients with Chronic Hepatitis B Virus Infection

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MENDHAM, N.J., and SOUTH SAN FRANCISCO, Calif, Oct. 19, 2021 (GLOBE NEWSWIRE) -- Antios Therapeutics, Inc. and Assembly Biosciences, Inc. (Nasdaq: ASMB) today announced that the companies have entered into a clinical collaboration agreement to evaluate a triple combination treatment in patients with chronic hepatitis B virus (HBV) infection. A single cohort in the ongoing Antios Phase 2a ANTT201 clinical trial will evaluate ATI-2173, Antios' investigational proprietary active site polymerase inhibitor nucleotide (ASPIN), vebicorvir (VBR), Assembly Bio's investigational lead core inhibitor candidate, and tenofovir disoproxil fumarate, a nucleotide reverse transcriptase inhibitor.

The multi-center, double-blinded, placebo-controlled cohort will evaluate the safety, pharmacokinetics, and antiviral activity of this all-oral triple combination. This cohort is expected to start in the first half of 2022 and will enroll 10 treatment naïve or off-treatment HBeAg negative or positive patients in a 12-week treatment study.

"Antios is focused on developing a functional cure for people living with chronic HBV. ATI-2173 has, to date, demonstrated a generally well-tolerated safety profile, leveraging a unique ASPIN mechanism in clinical development to empower combination therapy. Ultimately, ATI-2173 has the potential to become a cornerstone of a once-daily curative regimen in combination with other agents, like vebicorvir, for the treatment of chronic HBV," said Gregory Mayes, Chief Executive Officer of Antios.

"Our collaboration with Antios emphasizes our commitment to evaluating the backbone of our core inhibitors plus a nucleos(t)ide analogue in combination with other mechanisms to treat HBV, a cause of chronic infection that can lead to a higher risk of death from cirrhosis and liver cancer," said John McHutchison, AO, MD, Chief Executive Officer and President of Assembly Bio. "The commitment that we and Antios share to pursue finite and curative therapies for HBV unites us in these research efforts and offers hope for patients."

About ATI-2173
ATI-2173, Antios Therapeutics' lead once-daily, oral drug candidate for treating HBV, is an investigational phosphoramidate prodrug of clevudine monophosphate. ATI-2173 has the potential, if approved, to become the cornerstone of a curative HBV regimen. It is the only Active Site Polymerase Inhibitor Nucleotide (ASPIN) in clinical development and its mechanism of action is designed to be complementary to other approaches that also seek to achieve a functional cure. ATI-2173 is currently in Phase 2 clinical development. The SAVE-1 (Sustained Anti-Viral Efficacy) trial is an ongoing, double-blind, randomized, placebo-controlled study of 30 adult patients designed to assess the safety and efficacy of 25 and 50 mg doses of ATI-2173 daily for 90 days in combination with tenofovir disoproxil fumarate (TDF) compared with TDF plus ATI-placebo (control) in chronic HBV-infected subjects.

About Vebicorvir, Assembly Bio's Lead HBV Core Inhibitor
Assembly Bio's HBV portfolio includes three investigational small molecule candidates, all of which are HBV core inhibitors that target multiple steps of the HBV replication cycle. In Phase 2 clinical trials, first-generation core inhibitor vebicorvir (VBR) administered with nucleos(t)ide analogue reverse transcriptase inhibitor (NrtI) therapy demonstrated a favorable safety profile and led to greater viral suppression of both HBV DNA and HBV pgRNA than NrtI therapy alone. VBR is advancing in multiple Phase 2 combination studies.

About HBV
Chronic hepatitis B virus (HBV) infection is a debilitating disease of the liver that affects 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 Antios Therapeutics, Inc.

Antios Therapeutics is a clinical-stage biopharmaceutical company focused on the development of innovative therapies to treat and cure viral diseases. Its lead drug candidate ATI-2173 – the only Active Site Polymerase Inhibitor Nucleotide (ASPIN) in clinical development – has the potential, if approved, to become the cornerstone of a curative therapeutic regimen for chronic HBV, a major unmet global health problem affecting up to 300 million people worldwide, more than hepatitis C and HIV combined. For more information, please visit www.antiostherapeutics.com.

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 www.assemblybio.com.

Assembly Biosciences 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 HBV 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; 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 Assembly Bio's HBV 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.

ANTIOS CONTACTS

Investors:
Lee Roth
Burns McClellan
lroth@burnsmc.com
+1 (212) 300-8331

Media:
Jenny Hooper
JPA Health
jhooper@jpa.com
+1 (202) 899-5379 / +1 (956) 638-5095

ASSEMBLY BIO CONTACTS

Investors:
Lauren Glaser
Assembly Bio
lglaser@assemblybio.com
+1 (415) 521-3828

Media:
Audra Friis
Sam Brown Inc.

ASMBMedia@sambrown.com
+1 (917) 519-9577