Atea Pharmaceuticals Presents Multiple New Datasets Supporting the Combination of Bemnifosbuvir and Ruzasvir for the Treatment of Hepatitis C Virus at AASLD's The Liver Meeting 2024

November 15, 2024

BOSTON, Nov. 15, 2024 (GLOBE NEWSWIRE) -- Atea Pharmaceuticals, Inc. (Nasdaq: AVIR) ("Atea"), a clinical-stage biopharmaceutical company engaged in the discovery and development of oral antiviral therapeutics for serious viral diseases, today presented three poster presentations supporting the combination of bemnifosbuvir and ruzasvir as a potential treatment for hepatitis C virus (HCV). The combination of bemnifosbuvir, a nucleotide analog polymerase inhibitor, and ruzasvir, an NS5A inhibitor, is in Phase 2 development for the treatment of HCV. These data are being presented at the American Association for the Study of Liver Diseases' (AASLD) The Liver Meeting 2024, being held from November 15-19, 2024 in San Diego, CA.

"These important data presented today at The Liver Meeting add to the growing body of evidence supporting the combination of bemnifosbuvir and ruzasvir and its potential best-in-class profile for the treatment of HCV," said Jean-Pierre Sommadossi, PhD, Chief Executive Officer and Founder of Atea Pharmaceuticals. "We expect to report results from our Phase 2 study of the combination of bemnifosbuvir and ruzasvir in early December and we look forward to initiating Phase 3 development in early 2025. Our combination includes the most compelling attributes of current HCV drug treatments such as convenience, low risk for drug-drug interactions, as well as short duration, which is further supported by the viral kinetic modeling results presented today. We believe our combination has the potential to address current treatment challenges and unmet needs and to play a major role in the eradication of HCV."

"A multiscale model of HCV infection and treatment was designed to estimate the *in vivo* effectiveness of agents including various combinations of direct-acting antivirals to block HCV replication and viral assembly," said Alan Perelson, PhD, Senior Fellow at Los Alamos National Laboratory. "The data presented today modeling the combination of bemnifosbuvir and ruzasvir for the treatment of HCV align with the reported clinical results from the lead-in cohort of the Phase 2 study. These data are highly encouraging and show a SVR12 rate of 97% and support a short eight-week course of treatment."

Poster Number: 1467
Date and Time: Friday, November 15, 1:00 p.m. – 2:00 p.m. PT
Location: San Diego Convention Center
Title: Multiscale Modeling of Lead-in Results from a Phase 2 Study of an 8-Week Combination Regimen of Bemnifosbuvir and Ruzasvir in Patients with Chronic Hepatitis C Virus Infection
Presenter: Ruy M. Ribeiro, PhD

A multiscale HCV viral kinetic model was utilized to estimate the clinical effectiveness of the combination of bemnifosbuvir and ruzasvir in blocking HCV replication and viral assembly/secretion against HCV. This model evaluated the combination of bemnifosbuvir and ruzasvir in the lead-in cohort (n=60) of a Phase 2 single-arm study. This cohort was comprised of treatment-naïve, non-cirrhotic patients with chronic HCV receiving 550 mg bemnifosbuvir once daily (QD) and 180 mg ruzasvir QD for 8 weeks. The multiscale model was fit to the plasma viral load (VL) and the alanine aminotransferase (ALT) data from all 60 subjects simultaneously through mixed-effects population fitting.

The modeling results provided insight on the mechanism of action and demonstrated that the combination of bemnifosbuvir and ruzasvir was highly effective in blocking both viral replication and viral assembly/secretion in HCV-infected patients, independent of genotype, age, sex, or fibrosis score. A high sustained virologic response at 12 weeks post-treatment (SVR12) rate of 97% was observed in the Phase 2 lead-in cohort and the analysis supports the short eight-week treatment with bemnifosbuvir and ruzasvir for chronic HCV.

Poster Number: 1466
Date and Time: Friday, November 15, 1:00 p.m. – 2:00 p.m. PT
Location: San Diego Convention Center
Title: Bemnifosbuvir Does Not Alter Cardiac Repolarization in Healthy Participants: Results from a Thorough QT Study
Presenter: Xiao-Jian Zhou, PhD

Bemnifosbuvir had no clinically relevant effects on cardiac repolarization, heart rate, PR interval, or QRS duration (all related to heart function) in healthy volunteers (n=38). A QTc effect exceeding 10 milliseconds, the established threshold of concern, can be excluded across the observed plasma concentrations of bemnifosbuvir and its metabolites at the therapeutic and supratherapeutic doses.

Poster Number: 1501
Date and Time: Friday, November 15, 1:00 p.m. – 2:00 p.m. PT
Location: San Diego Convention Center
Title: Bemnifosbuvir Poses High Barrier for Resistance in Both Preclinical and Phase 1b Monotherapy Studies
Presenter: Qi Huang, PhD

Next generation sequencing was performed to determine bemnifosbuvir resistant substitutions in a Phase 1b study (n=42) that had demonstrated potent antiviral activity of bemnifosbuvir when used as a monotherapy in HCV genotype 1b, 2a and 3a infected patients. Time-related, dose-related, and exposure-related decreases in HCV RNA were observed after multiple doses of bemnifosbuvir. The pre-existing NS5B non-nucleoside resistance-associated substitutions at baseline did not correlate to bemnifosbuvir antiviral activity based on the maximum HCV RNA reduction of each subject.

The changes of amino acid percentage in on-treatment samples were generally minimal, within 1-2% compared with baseline samples, indicating no development of viral resistance.

About Bemnifosbuvir and Ruzasvir for Hepatitis C Virus (HCV)

Bemnifosbuvir has been shown in *in vitro* studies to be approximately 10-fold more active than sofosbuvir (SOF), against a panel of laboratory strains and clinical isolates of HCV GT 1–5. *In vitro* studies have also demonstrated bemnifosbuvir remained fully active against SOF resistance-associated substitutions (S282T), with up to 58-fold more potency than SOF. The pharmacokinetic (PK) profile of bemnifosbuvir supports once-daily dosing for the treatment of HCV. Bemnifosbuvir has been shown to have a low risk for drug-drug interactions. Bemnifosbuvir has been administered to over 2,200 subjects and has been well-tolerated at doses up to 550 mg for durations up to 12 weeks in healthy subjects and patients.

Ruzasvir has demonstrated highly potent and pan-genotypic antiviral activity in preclinical (picomolar range) and clinical studies. Ruzasvir has been administered to over 1,500 HCV-infected patients at daily doses of up to 180 mg for 12 weeks and has demonstrated a favorable safety profile. The PK profile of ruzasvir supports once-daily dosing.

About Hepatitis C Virus (HCV)

Hepatitis C Virus (HCV) is a blood-borne, positive-sense, single-stranded (ss)RNA virus that primarily infects liver cells. HCV is a leading cause of chronic liver disease and liver transplants, spreading via blood transfusion, hemodialysis and needle sticks. An estimated 50 million people globally live with chronic HCV infection, with approximately 1 million new infections and 242,000 deaths occurring each year. Most HCV-related deaths are due to liver scarring (cirrhosis) and liver cancer (hepatocellular carcinoma). Injection drug use accounts for around 30% of new HCV cases globally and approximately 60% in the U.S., where between 2-4 million people are estimated to have HCV. Annually, HCV diagnoses in the U.S. outpace treatment rates, as less than a third of those diagnosed with HCV receive timely treatment.

About Atea Pharmaceuticals

Atea is a clinical-stage biopharmaceutical company focused on discovering, developing and commercializing oral antiviral therapies to address the unmet medical needs of patients with serious viral infections. Leveraging Atea's deep understanding of antiviral drug development, nucleos(t)ide chemistry, biology, biochemistry and virology, Atea has built a proprietary nucleos(t)ide prodrug platform to develop novel product candidates to treat single stranded ribonucleic acid, or ssRNA, viruses, which are a prevalent cause of serious viral diseases. Atea plans to continue to build its pipeline of antiviral product candidates by augmenting its nucleos(t)ide platform with other classes of antivirals that may be used in combination with its nucleos(t)ide product candidates. Our lead program and current focus is on the development of the combination of bemnifosbuvir, a nucleotide analog polymerase inhibitor, and ruzasvir, an NS5A inhibitor, to treat HCV. For more information, please visit www.ateapharma.com.

Forward-Looking Statements

This press release includes "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements in this press release include but are not limited to the anticipated date and time of the presentations at The Liver Meeting, the anticipated timing for reporting of the results from Atea's Phase 2 clinical trial of the combination of bemnifosbuvir and ruzasvir in the treatment of hepatitis C and the anticipated advancement of the program into Phase 3 clinical development. When used herein, words including "expect," "plans", and similar expressions are intended to identify forward-looking statements. In addition, any statements or information that refer to expectations, beliefs, plans, projections, objectives, performance or other characterizations of future events or circumstances, including any underlying assumptions, are forward-looking. All forward-looking statements are based upon Atea's current expectations and various assumptions. Atea believes there is a reasonable basis for its expectations and beliefs, but they are inherently uncertain. Atea may not realize its expectations, and its beliefs may not prove correct. Actual results could differ materially from those described or implied by such forward-looking statements as a result of various important factors, including, without limitation, dependence on the success of Atea's most advanced product candidates, in particular the combination of bemnifosbuvir and ruzasvir for the treatment of hepatitis C; as well as the other important factors discussed under the caption "Risk Factors" in Atea's Quarterly Report on Form 10-Q for the quarter ended September 30, 2024 as such factors may be updated from time to time in its other filings with the SEC, which are accessible on the SEC's website at www.sec.gov. These and other important factors could cause actual results to differ materially from those indicated by the forward-looking statements made in this press release. Any such forward-looking statements represent management's estimates as of the date of this press release. While Atea may elect to update such forward-looking statements at some point in the future, except as required by law, it disclaims any obligation to do so, even if subsequent events cause our views to change. These forward-looking statements should not be relied upon as representing Atea's views as of any date subsequent to the date of this press release.

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