Atea Pharmaceuticals Announces Positive Results from Phase 2 Study of Bemnifosbuvir and Ruzasvir Regimen for Treatment of Hepatitis C Virus (HCV)

December 4, 2024

Primary Endpoint Achieved with 98% Sustained Virologic Response at 12 Weeks Post-Treatment (SVR12) after Short Eight Week Treatment Duration

Regimen Was Generally Safe and Well-Tolerated

Global Phase 3 Program Initiation Expected Early in 2025

BOSTON, Dec. 04, 2024 (GLOBE NEWSWIRE) -- Atea Pharmaceuticals, Inc. (Nasdaq: AVIR) ("Atea" or "Company"), a clinical-stage biopharmaceutical company engaged in the discovery and development of oral antiviral therapeutics for serious viral diseases, today announced that the Company's Phase 2 study of the regimen of bemnifosbuvir, a nucleotide analog polymerase inhibitor, and ruzasvir, an NS5A inhibitor, for treatment of hepatitis C virus (HCV) met its primary endpoints of safety and sustained virologic response at 12 weeks post-treatment (SVR12).

Primary endpoint results demonstrated a 98% (208/213) SVR12 rate in the per-protocol treatment adherent patient population after eight weeks of treatment with a regimen of bemnifosbuvir and ruzasvir. The efficacy evaluable patient population, which included 17% treatment non-adherent patients, achieved a 95% (242/256) SVR12 rate demonstrating the robust potency and forgiveness of the regimen. The regimen was generally safe and well-tolerated with no drug-related serious adverse events or treatment discontinuations. An accompanying slide deck with the topline Phase 2 results is available on Atea's website here. Full data for the Phase 2 study are anticipated to be presented at a scientific meeting during the first half of 2025.

"These high SVR12 results with only eight weeks of treatment with our regimen are extremely exciting and very significant given the unmet needs for today's HCV patients. We are eager to discuss our program with regulators, including the U.S. Food and Drug Administration, to promptly advance to Phase 3 development early next year," said Jean-Pierre Sommadossi, PhD, Chief Executive Officer and Founder of Atea. "The HCV market continues to be underserved, and HCV diagnoses in the U.S. outpace treatment rates annually. Our regimen has a potential best-in-class profile that includes the key features for successfully treating today's HCV patients including convenience, low risk for drug-drug interactions and short treatment duration. We believe that this regimen has the potential to play a major role in the eradication of HCV in the U.S."

In the Phase 2 study, 99% (178/179) of treatment adherent patients who were non-cirrhotic and infected with genotypes 1-4 achieved SVR12, demonstrating robust pan-genotypic potency and supporting an eight-week treatment in the Phase 3 program. Treatment adherent patients with cirrhosis achieved a 88% (30/34) SVR12 rate. Viral kinetics were slower in these cirrhotic patients, however, all patients achieved 100% end of treatment response. To maximize efficacy, treatment duration in patients with cirrhosis will be 12 weeks in the Phase 3 program. Based on the high proportion of people between 20-49 years old who are infected with HCV combined with the low and declining incidence of cirrhosis in newly-infected patients in the U.S., it is estimated that less than 10% of the HCV patient population has cirrhosis.

"I've experienced first-hand the changing population of HCV patients and the increasing importance of short duration therapy," said Eric Lawitz, MD, The Texas Liver Institute, Clinical Professor of Medicine, University of Texas Health San Antonio. "Our current HCV patients are younger, and frequently taking concurrent medications for their comorbidities. More recently, there are also fewer patients presenting with cirrhosis. I'm encouraged by these promising Phase 2 results and look forward to the Phase 3 program."

Atea is currently preparing for the Phase 3 program, which is expected to follow an End of Phase 2 meeting with the U.S. Food and Drug Administration (FDA) anticipated for early 2025. It is expected that the Phase 3 program will use a fixed dose combination (FDC) tablet reducing the daily pill count from four to two tablets, enhancing patient convenience, with no food effect.

About the Phase 2 Study

The global Phase 2 study enrolled 275 treatment-naïve patients, both with and without compensated cirrhosis. The study was designed to evaluate the safety and efficacy of eight weeks of treatment with the regimen consisting of once-daily bemnifosbuvir 550 mg and ruzasvir 180 mg.

The primary endpoints of the study are safety and SVR12 in the per-protocol treatment adherent population. Secondary and other endpoints include SVR12 in the per-protocol population regardless of treatment adherence (efficacy evaluable), virologic failure and 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. It is estimated that less than 10% of patients in the U.S. infected with HCV have cirrhosis. 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 fixed dose combination regimen 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 advancement of the program into Phase 3 clinical development and potential contribution of the regimen of bemnifosbuvir and ruzasvir to the goal of elimination of HCV in the U.S. When used herein, words including "will," "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.

Contacts

Jonae Barnes
SVP, Investor Relations and Corporate Communications
617-818-2985
Barnes.jonae@ateapharma.com

Will O'Connor
Precision AQ
212-362-1200
will.oconnor@precisionaq.com