Atea Pharmaceuticals Announces First Patient Dosed in Phase 2 Study for Treatment of Hepatitis C with Bemnifosbuvir and Ruzasvir Combination

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Combination Offers Opportunity to Improve Standard of Care with Potential for Short Duration, Protease Inhibitor-Free Treatment

BOSTON, June 15, 2023 (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 announced the dosing of the first patient in the Phase 2 bemnifosbuvir and ruzasvir combination study for the treatment of Hepatitis C Virus (HCV) infection.

"The initiation of this Phase 2 combination study marks an important clinical milestone for Atea," said Jean-Pierre Sommadossi, PhD, Chief Executive Officer and Founder of Atea Pharmaceuticals. "We believe the combination of bemnifosbuvir and ruzasvir has the potential to significantly improve upon the current standard of care by offering a short duration, pan-genotypic, protease inhibitor-free treatment for patients with HCV, with or without cirrhosis."

The open label Phase 2 study is designed to enroll approximately 280 HCV-infected, direct-acting antiviral naive patients across all genotypes, including a 60 patient lead-in cohort. Patients will be administered 550 mg bemnifosbuvir in combination with 180 mg ruzasvir once-daily for eight weeks. The primary endpoints of the study are safety and sustained virologic response (SVR) at Week 12 post-treatment. Other virologic endpoints include virologic failure, SVR at Week 24 post-treatment and resistance. Preliminary data from the 60 patient lead-in cohort are anticipated in the fourth quarter of 2023.

"Despite significant treatment advances, there remains a large, underserved HCV patient population that continues to grow dramatically due to the opioid crisis, injection drug use and HCV reinfection. According to the World Health Organization, an estimated 58 million people globally have chronic HCV infection, about 1.5 million new infections occur per year and nearly 300,000 people die every year from HCV-related liver diseases," added Dr. Sommadossi.

About Hepatitis C Virus (HCV)

HCV is a blood-borne, positive sense, single stranded RNA virus, primarily infecting cells of the liver. HCV is a leading cause of chronic liver disease and liver transplants and spreads via blood transfusion, hemodialysis and needle sticks. In the United States, injection drug use accounts for approximately 60% of all new cases of HCV. Diagnosis of HCV is made through blood tests, including molecular tests that allow for the detection, quantification and analysis of viral genomes and the classification of an infection into specific viral genotypes. Infection becomes chronic in 75% to 85% of cases, with an incubation period lasting from two to 26 weeks.

HCV is classified into seven genotypes and 67 subtypes, with genotype 1 being responsible for more than 70% of HCV cases in the United States. Patients with HCV are also classified by liver function status: compensated cirrhosis (liver scarring) denotes those patients that do not yet have impaired liver function, while decompensated cirrhosis describes patients with moderate to severe liver function impairment.

The HCV patient population continues to grow dramatically in the United States. A large portion of the current increase in incidence is attributable to the opioid crisis, injection drug use and HCV reinfection. The prevalence of HCV in the US is expected to continue to remain steady over the coming years as rising HCV incidence offsets the number of new patients treated. The HCV market is estimated at approximately $3.5 billion in global net sales in 2022, with approximately 50% attributable to the US.

About Bemnifosbuvir and Ruzasvir for Hepatitis C Virus

Bemnifosbuvir has been shown to be approximately 10-fold more active than sofosbuvir (SOF) *in vitro* against a panel of laboratory strains and clinical isolates of HCV genotypes 1–5. *In vitro* studies demonstrated bemnifosbuvir remained fully active against SOF resistant S282T and GT1a/3a NS5A resistance associated variants (RAVs) tested and was shown to be at least 10 times more potent than SOF. In clinical studies to date, the pharmacokinetic (PK) profile of bemnifosbuvir supports once-daily dosing for the treatment of HCV and bemnifosbuvir has been well tolerated at doses up to 550 mg for durations up to 8-12 weeks in healthy and HCV infected subjects. Rapid and highly potent pan-genotypic antiviral activity was observed with bemnifosbuvir in HCV infected subjects, regardless of cirrhosis status.

Ruzasvir (RZR), an oral NS5A inhibitor, has demonstrated highly potent and pan-genotypic antiviral activity in preclinical (picomolar range) and clinical studies. *In vitro*, ruzasvir retained high potency against GT1a/3a NS5A RAVs and was shown to be 5 to10-fold more potent than velpatasvir. Ruzasvir has been administered to over 1,200 HCV-infected patients at daily doses of up to 180 mg for up to 24 weeks and has demonstrated a favorable safety profile. Ruzasvir's PK profile supports once-daily dosing. The combination of bemnifosbuvir and ruzasvir for the treatment of HCV is in Phase 2 development.

About Atea Pharmaceuticals

Atea is a clinical stage biopharmaceutical company focused on discovering, developing and commercializing oral therapies to address the unmet medical needs of patients with serious viral infections. Leveraging the Company's deep understanding of antiviral drug development, nucleos(t)ide chemistry, biology, biochemistry and virology, Atea is developing 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 through using its

internal discovery capabilities augmented by in-licensing. Currently, Atea is focused on the development of orally-available antiviral agents for serious viral infections, including severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), the virus that causes COVID-19, and hepatitis C virus (HCV). For more information, please visit www.ateapharma.com.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements contained in this press release that do not relate to matters of historical fact should be considered forward-looking statements, including without limitation statements regarding our expectations surrounding the potential of our product candidates, and expectations regarding our pipeline, including trial design and development timelines. These statements are neither promises nor guarantees, but involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements, including, but not limited to, the uncertainty around and costs associated with the clinical development of the combination of bemnifosbuvir and ruzasvir as a potential treatment for HCV. These and other important factors discussed under the caption “Risk Factors” in our Annual Report on Form 10-K for the year ended December 31, 2022 and our other filings with the SEC 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 we may elect to update such forward-looking statements at some point in the future, we disclaim any obligation to do so, even if subsequent events cause our views to change.

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