Atea Pharmaceuticals Presents New Data Showcasing Potential Best-in-Class Combination Profile of Bemnifosbuvir and Ruzasvir for Treatment of Hepatitis C Virus at EASL Congress 2024

May 22, 2024

Presentations to Include New Antiviral Efficacy Results, Including SVR12 Data, from Lead-In Cohort of Ongoing Phase 2 HCV Trial

Data Also Highlight the High Prevalence of Pre-Existing NS5A Resistance-Associated Substitutions (RAS) Detected in HCV-infected Patients

BOSTON, May 22, 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 announced the Company will present new efficacy results, including SVR12 data (primary endpoint), from the Phase 2 lead-in cohort evaluating the combination of bemnifosbuvir (an oral nucleotide NS5B polymerase inhibitor) and ruzasvir (an oral NS5A inhibitor) for the treatment of hepatitis C virus (HCV) at the European Association for the Study of the Liver (EASL) Congress 2024, taking place June 5-8, 2024 in Milan, Italy. Preclinical data further demonstrating bemnifosbuvir's high barrier to resistance and pharmacokinetics and ruzasvir's low risk of drug-drug interactions will also be presented.

"Despite current HCV treatments, progress toward eliminating the virus in the U.S. has slowed, and new chronic cases exceed cure rates. In the decade since the first direct acting antiviral treatments were introduced, both the virus and the patient population have changed significantly, including the emergence of resistant mutations," said Jean-Pierre Sommadossi, PhD, Chief Executive Officer and Founder of Atea Pharmaceuticals. "We need new HCV treatments that address the needs of today's patients and feature a best-in-class treatment profile with high antiviral potency, short treatment duration, potential for low risk of drug-drug interactions and a high barrier to resistance. We look forward to sharing our data at EASL Congress 2024, which will reinforce the potential of this combination to treat HCV as it exists today."

More than 2 million people in the U.S. are living with chronic HCV, and approximately 100,000 new chronic cases are diagnosed each year. HCV diagnoses continually outpace annual cure rates, as less than a third of those diagnosed with HCV receive timely treatment. As HCV persists, six main variants, or genotypes, have emerged. Genotype 1 is the most prevalent, while some variants, such as genotype 3, can be more difficult to treat due to mutations that enable the virus to develop resistance against existing HCV drugs.

The full datasets for the accepted abstracts will become available on the EASL Congress website following the embargo lift on Wednesday, June 5th at 8:00 AM Central European Time (CEST).

Details for the EASL Congress presentations are as follows:

Poster ID: THU-382
Title: Lead-in Cohort Results From a Phase 2 Study of a Novel 8-Week Combination Regimen of Bemnifosbuvir and Ruzasvir in Patients with Chronic Hepatitis C Virus Infection
Presenting Author: Alina Jucov, M.D., Ph.D.
Date and Time: June 6, 2024, 8:30 AM CEST

Poster ID: SAT-402
Title: Bemnifosbuvir is a Potent HCV NS5B Inhibitor with a Favorable Antiviral Profile and High Resistance Barrier
Presenting Author: Qi Huang, Ph.D.
Date and Time: June 8, 2024, 8:30 AM CEST

Poster ID: SAT-411
Title: Absorption, Distribution, Metabolism, and Excretion of [14C]-Bemnifosbuvir in Rats
Presenting Author: Alex Vo, Ph.D.
Date and Time: June 8, 2024, 8:30 AM CEST

Poster ID: SAT-412
Title: Low Risk of Drug-Drug Interactions for Ruzasvir Based Upon *In Vitro* Metabolism and Transporter Interaction Studies
Presenting Author: Alex Vo, Ph.D.
Date and Time: June 8, 2024, 8:30 AM CEST

About Bemnifosbuvir and Ruzasvir for Hepatitis C Virus (HCV)

Bemnifosbuvir is an oral, purine nucleotide prodrug designed to inhibit viral replication by impairing viral RNA polymerase, a key component in the replication machinery of enveloped positive single-stranded RNA viruses, such as human coronaviruses and HCV. Atea is developing bemnifosbuvir in combination with ruzasvir, an oral NS5A inhibitor for the treatment of HCV. As single agents, both bemnifosbuvir and ruzasvir have demonstrated potent pan-genotypic antiviral activity against HCV. The combination of bemnifosbuvir and ruzasvir has exhibited synergistic *in vitro* activity against HCV with no pharmacokinetic (PK) drug-drug interactions in healthy volunteers.

In vitro studies have shown bemnifosbuvir 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 that bemnifosbuvir remained fully active against SOF resistance-associated strains (S282T), with up to 58-fold more potency than SOF. The PK profile of bemnifosbuvir supports once-daily dosing for the treatment of HCV.

Across both HCV and COVID-19 programs, bemnifosbuvir has been administered to over 2,100 subjects and has been well-tolerated at doses up to 550 mg for durations up 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 1,200 HCV-infected patients at daily doses of up to 180 mg for up to 12 weeks and has demonstrated a favorable safety profile. Ruzasvir's PK profile supports once-daily dosing.

About the Phase 2 Study

Atea is currently conducting a global Phase 2 clinical trial of bemnifosbuvir in treatment-naïve, chronic HCV-infected patients either without cirrhosis or with compensated cirrhosis. This study is designed to evaluate the safety and efficacy of eight weeks of treatment with the combination consisting of once-daily bemnifosbuvir 550 mg and ruzasvir 180 mg. Up to approximately 280 chronically infected, treatment-naïve patients across all HCV genotypes, including the lead-in cohort of 60 patients without cirrhosis, are expected to be enrolled in this Phase 2 clinical trial.

The primary endpoints of the study are safety and sustained virologic response (SVR) at Week 12 post-treatment (SVR12). Other virologic endpoints include virologic failure, SVR at Week 24 post-treatment (SVR24) and resistance. Results from the 60-patient lead-in cohort announced in February 2024 demonstrated a 98% SVR4 rate across genotypes from 58 of 59 patients, which include a patient with poor adherence who did not achieve SVR4 and exclude one patient who did not attend the Week 4 post-treatment follow-up. Topline results from all patients enrolled in the Phase 2 study are anticipated in the second half of 2024.

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 the Company'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. Currently, Atea is focused on the development of orally-available antiviral agents for 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 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 Company's plans relating to the date and time of the presentations at the conference and the potential of bemnifosbuvir in combination with ruzasvir to treat HCV if successfully developed. trial results. When used herein, words including "expects," "may," "will," "anticipates," "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 the Company's current expectations and various assumptions. The Company believes there is a reasonable basis for its expectations and beliefs, but they are inherently uncertain. The Company 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, the important factors discussed and updated from time to time under the caption "Risk Factors" in the reports the Company files with the SEC, including annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and other filings each of 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 the Company 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 the Company's views as of any date subsequent to the date of this press release.

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