Atea Pharmaceuticals Presents Promising Bemnifosbuvir and Ruzasvir Combination Data for the Treatment of Hepatitis C Virus at AASLD The Liver Meeting 2023

November 13, 2023

First Clinical Data for Coadministration of Bemnifosbuvir and Ruzasvir Show Combination Was Well Tolerated in a Phase 1 Study

Plasma Pharmacokinetic (PK) Profiles of Bemnifosbuvir and Ruzasvir Were Not Affected by Food or Concomitant Dosing, Indicating Low Risk of Drug-Drug Interactions

Bemnifosbuvir and Ruzasvir are Potent Direct Acting Antivirals In Vitro with Favorable Antiviral Profiles Against HCV NS5A and NS5B Resistant Associated Variants (RAVs)

BOSTON, Nov. 13, 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 presentation of two posters supporting the combination of bemnifosbuvir, an oral nucleotide polymerase inhibitor, and ruzasvir, an oral NS5A inhibitor, as a potential treatment for Hepatitis C Virus (HCV) at the American Association for the Study of Liver Diseases' (AASLD) The Liver Meeting 2023, being held from November 10-14, 2023 in Boston, MA.

"Results from these two presented studies further support the potential use of these two drug candidates in combination as a novel treatment for HCV. Phase 1 data demonstrate that coadministration of bemnifosbuvir and ruzasvir was well tolerated and not affected by food or concomitant dosing, indicating a low risk of drug-drug interactions," said Jean-Pierre Sommadossi, PhD, Chief Executive Officer and Founder of Atea Pharmaceuticals. "Moreover, *in vitro* data demonstrate that the combination of bemnifosbuvir and ruzasvir retained potent pan-genotypic antiviral activity against major HCV NS5A and NS5B resistance-associated variants and hard-to-treat sub-genotypes, which have been identified in certain HCV patients who have failed treatment with currently available therapies."

"We are very pleased with the substantial progress achieved in our Phase 2 combination study of bemnifosbuvir and ruzasvir for the treatment of HCV this year, and we expect to announce results from the 60-person lead-in cohort in early 2024," continued Dr. Sommadossi. "We look forward to progressing the clinical development of this potent direct-acting antiviral combination for the potential benefit for millions of patients who, despite available treatments for HCV, remain underserved."

Poster Number: 1879-A
Date and Time: Friday, November 10, 1:00 p.m. – 2:00 p.m.
Location: Hall A
Title: Lack of Pharmacokinetic Drug-Drug Interaction Between Bemnifosbuvir and Ruzasvir in Healthy Participants

Results from a Phase 1 study in 32 healthy adult participants demonstrate that the coadministration of bemnifosbuvir and ruzasvir was well tolerated, and plasma pharmacokinetic (PK) profiles remained generally unaffected by food or concomitant dosing, indicating a lack of drug-drug interaction between the two drug candidates. Two cohorts (n=16) were dosed at either (i) 550 mg bemnifosbuvir once-daily for 18 days and 180 mg ruzasvir once-daily starting at Day 7 through Day 18 or (ii) 180 mg ruzasvir once daily for 18 days and bemnifosbuvir 550 mg once-daily starting at Day 7 through Day 18. No deaths or serious treatment-emergent adverse events (TEAEs) were reported and no participants withdrew due to a TEAE. These Phase 1 data support the continued clinical evaluation of these two potent drug candidates in combination for the treatment of HCV.

Poster Number: 1861-A
Date and Time: Friday, November 10, 1:00 p.m. – 2:00 p.m.
Location: Hall A
Title: Bemnifosbuvir and Ruzasvir are Potent HCV DAAs with Favorable Antiviral Profiles Against Major HCV NS5A and NS5B RAVs Supporting Use in Combination

Results from an *in vitro* study demonstrate that the combination of bemnifosbuvir and ruzasvir has potent pan-genotypic antiviral activity against major HCV NS5A and NS5B RAVs and hard-to-treat sub-genotypes. Furthermore, results demonstrate that bemnifosbuvir is approximately 10-fold more potent than sofosbuvir (SOF) and retained full potency against all HCV GT-1a and GT-3a NS5A RAVs tested. Based on these *in vitro* results combined with other data to date, the combination of bemnifosbuvir and ruzasvir is expected to retain antiviral activity against major clinically relevant HCV NS5A and NS5B RAVs. The combination of bemnifosbuvir and ruzasvir has the potential to be a promising treatment option for HCV infection, given the potent, pan-genotypic antiviral activity of bemnifosbuvir and ruzasvir, the high resistance barrier of bemnifosbuvir, previously reported clinical safety and antiviral activity data for each drug candidate when administered individually, lack of drug-drug interactions between the two drug candidates, and complementary mechanisms of actions.

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 was approximately $3.5 billion in global net sales in 2022, with approximately 50% of such net sales attributable to the US.

About Bemnifosbuvir and Ruzasvir for Hepatitis C Virus (HCV)

Bemnifosbuvir, an oral nucleotide polymerase inhibitor, has been shown to be approximately 10-fold more potent than 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 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 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.

RZR, an oral NS5A inhibitor, has demonstrated highly potent and pan-genotypic antiviral activity in preclinical (picomolar range) and clinical studies. RZR has been administered to over 1,200 HCV-infected patients at daily doses of up to 180 mg for 12 weeks and has demonstrated a favorable safety profile. RZR's PK profile supports once-daily dosing.

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 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, including the combination of bemnifosbuvir and ruzasvir for the treatment of HCV. 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. 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.

Contacts

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

Will O'Connor
Stern Investor Relations
212-362-1200
will.oconnor@sternir.com