Atea Pharmaceuticals Announces Presentation of Bemnifosbuvir Preclinical Data at the 38th International Conference on Antiviral Research (ICAR) 2025

March 19, 2025

BOSTON, March 19, 2025 (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 the poster presentation of bemnifosbuvir preclinical data at the 38th International Conference on Antiviral Research (ICAR) 2025 taking place March 17-21, 2025 in Las Vegas, Nevada.

“The results presented at ICAR highlight Atea’s deep scientific expertise in antiviral drug development by demonstrating metabolism of nucleotide prodrugs, such as bemnifosbuvir, is highly cell-line dependent and cell model selection needs to be taken into account when evaluating *in vitro* antiviral efficacy,” said Jean-Pierre Sommadossi, PhD, Chief Executive Officer and founder of Atea. “Bemnifosbuvir is being developed in a fixed dose combination regimen with ruzasvir for the treatment of hepatitis C virus (HCV). We look forward to starting patient enrollment in the Phase 3 program evaluating this potential best-in-class HCV regimen in April.”

Details for the poster presentation are as follows:

Poster Number: 500

Date and Time: Tuesday, March 18, 2025, 5:30 - 7:30 PM PDT and Thursday, March 20, 2025, 8:00 - 10:00 AM PDT

Title: Metabolism of Bemnifosbuvir to its Active Triphosphate Metabolite AT-9010 is Cell-Line Dependent

Bemnifosbuvir (BEM), an oral prodrug of a 6-modified guanosine nucleotide analog, is a potent HCV NS5B inhibitor being developed in a fixed dose combination regimen with ruzasvir, a highly potent NS5A inhibitor for the treatment of chronic HCV infection. The activation of BEM is mediated by cellular enzymes including CatA/CES1, HINT1, ADALP1, GUK1, and NDPK to yield the intracellular active triphosphate metabolite AT-9010. In this preclinical study, the metabolism of BEM to its active triphosphate was demonstrated to be cell-line dependent, indicating that cell model selection is critical when evaluating *in vitro* efficacy of antiviral prodrugs such as BEM.

Global Phase 3 Program for Hepatitis C Virus (HCV)

Based upon a successful engagement with the US Food and Drug Administration (FDA) at the End-of-Phase 2 meeting in January 2025, Atea is initiating a global Phase 3 program and expects patient enrollment to start in April 2025.

In December 2024, Atea announced that its Phase 2 study evaluating the regimen of BEM and ruzasvir for the treatment of HCV, met its primary endpoints. Atea plans to conduct two open label Phase 3 trials, one in the US and Canada and one outside of North America. Each Phase 3 trial is expected to enroll approximately 800 treatment-naïve patients, including those with and without compensated cirrhosis. For patients without cirrhosis, 8 weeks of the regimen of BEM and ruzasvir will be compared to 12 weeks of the regimen of sofosbuvir (SOF) and velpatasvir. For patients with compensated cirrhosis, 12 weeks of the regimen of BEM and ruzasvir will be compared to 12 weeks of the regimen of sofosbuvir and velpatasvir. In the US, it is estimated that more than 90% of people with HCV are non-cirrhotic.

The primary endpoint for both trials encompasses sustained virologic response 12 weeks post-treatment (SVR12) in each arm and is HCV RNA < lower limit of quantitation (LLOQ) 24 weeks from the start of treatment. Measurement at 24 weeks from the start of treatment is selected to ensure the primary endpoint occurs at the same relative timepoint from start of treatment in all patients.

About Bemnifosbuvir and Ruzasvir for Hepatitis C Virus (HCV)

BEM has been shown in *in vitro* studies to be approximately 10-fold more active than SOF against a panel of laboratory strains and clinical isolates of HCV GT 1–5. *In vitro* studies have also demonstrated BEM remained fully active against SOF resistance-associated substitutions (S282T), with up to 58-fold more potency than SOF. The PK profile of bemnifosbuvir supports once-daily dosing for the treatment of HCV. BEM has been shown to have a low risk for drug-drug interactions. BEM has been administered to over 2,300 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 2,100 subjects 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)

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, with 242,000 deaths occurring each year. Despite the availability of direct-acting antivirals, HCV continues to be a significant global healthcare issue. An estimated 50 million people worldwide are chronically infected with HCV and there are approximately one million new infections each year. In the US, between 2.4 and 4 million people are estimated to have HCV with annual new infections outpacing treatment rates. HCV infections in the US predominate in patients in the age group between 20-49 years old, and it is estimated that less than 10% of HCV-infected patients in the US have cirrhosis. Chronic HCV infection is the leading

cause of liver cancer in the US, Europe and Japan.

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 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 statements regarding the development of the regimen of bemnifosbuvir and ruzasvir for the treatment of HCV, including the anticipated initiation of patient enrollment in the Phase 3 program, and the potential best in class profile of the regimen . When used herein, words including "expected," "should," "anticipated," "believe." "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, the timeline for the completion of the strategic alternatives review process is unknown and there can be no assurance that the process will result in any particular outcome; 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 Annual Report on Form 10-K for the year ended December 31, 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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