Atea Pharmaceuticals to Present New Data Showcasing Potential Best-in-Class Regimen of Bemnifosbuvir and Ruzasvir for Treatment of Hepatitis C Virus at EASL Congress 2025

April 23, 2025

BOSTON, April 23, 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 that the full results from the Phase 2 clinical study of Atea's regimen of bemnifosbuvir, a nucleotide analog polymerase inhibitor, and ruzasvir, an NS5A inhibitor, for the treatment of hepatitis C virus (HCV) infection will be presented at the European Association for the Study of the Liver (EASL) Congress 2025. In addition, pharmacokinetic and safety results supporting the regimen's profile will also be presented. The EASL Congress 2025 will take place May 7-10 in Amsterdam, Netherlands.

The abstract detailing the results of the Phase 2 clinical trial (TOP-251) was identified by the EASL Congress as a top poster and selected for the "Poster Tour: Viral Hepatitis C: Clinical Aspects Including Follow Up After SVR & Therapy and Resistance" which also allows the poster to be displayed throughout the entire time of the event. The presentation of the full Phase 2 clinical results will highlight the efficacy and safety of the regimen of bemnifosbuvir and ruzasvir and its potential best-in-class profile, which includes short treatment duration, low risk for drug-drug interactions and convenience with no food effect. Atea has previously announced that the Phase 2 clinical trial met its primary endpoints of efficacy and safety.

"Atea is dedicated to developing a best-in-class regimen addressing the diverse needs of individuals living with hepatitis C," said Jean-Pierre Sommadossi, PhD, Chief Executive Officer and founder of Atea Pharmaceuticals. "Following our successful Phase 2 study and the recent initiation of our global Phase 3 program, we look forward to delivering the regimen of bemnifosbuvir and ruzasvir which we believe has the potential to increase the number of HCV patients that are treated and cured. Untreated chronic HCV can have a profound impact on patients' lives, as well as the associated healthcare and hospitalization costs, as the disease progresses in some cases to liver cancer."

Despite the availability of direct-acting antivirals, HCV continues to be a significant global health burden. 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. Chronic HCV infection is the leading cause of liver cancer in the US, Europe and Japan.

The accepted abstracts will become available on the EASL Congress 2025 website following the embargo lift on Wednesday, April 23rd at 8:00 AM Central European Time (CEST). Details for the EASL Congress 2025 presentations are as follows:

Poster ID: TOP-251
Title: Efficacy and Safety of Bemnifosbuvir and Ruzasvir after 8 Weeks of Treatment in Patients with Chronic Hepatitis C Virus (HCV) Infection
Presenting Author: Alina Jucov
Date and Time: Wednesday, May 7th, 8:30 AM CEST through Saturday, May 10th, 12:45 PM -1:45 PM CEST, Poster Tour May 10th, 12:45 PM -1:45 PM CEST, Track Hub 5 - Viral Hepatitis

Poster ID: WED-278
Title: Pharmacokinetics of Bemnifosbuvir in Participants with Hepatic Impairment
Presenting Author: Xiao-Jian Zhou
Date and Time: Wednesday, May 7th, 8:30 AM – 5:00 PM CEST

Poster ID: WED-279
Title: No Drug-Drug Interaction (DDI) Between Bemnifosbuvir/Ruzasvir and Bictegravir/Emtricitabine/Tenofovir Alafenamide
Presenting Author: Xiao-Jian Zhou
Date and Time: Wednesday, May 7th, 8:30 AM – 5:00 PM CEST

Poster ID: WED-280
Title: Pharmacokinetics of Bemnifosbuvir in Participants with Renal Impairment
Presenting Author: Xiao-Jian Zhou
Date and Time: Wednesday, May 7th, 8:30 AM – 5:00 PM CEST

HCV KOL Investor Event at 10:00 AM ET on May 14, 2025

Following the EASL Congress 2025, Atea will host a virtual key opinion leader (KOL) investor event with a panel of HCV experts and prescribers on Wednesday, May 14, 2025, at 10:00 AM ET. To register, click here.

This event will include several US and ex-US physicians who are leaders in hepatology / gastroenterology / infectious diseases and HCV treatments. These experts and prescribers will discuss the current challenges encountered by patients with HCV, the results from Atea's global Phase 2 study evaluating the regimen of bemnifosbuvir and ruzasvir for the treatment of HCV, which met its primary endpoints, and what a new optimized HCV therapy could provide for prescribers and patients. Company management will discuss the HCV commercial market opportunity and the ongoing global Phase 3 clinical development.

About the Phase 3 C-BEYOND and C-FORWARD Trials in Adults with Chronic HCV

As a part of its Phase 3 registrational program, Atea is conducting two open-label Phase 3 trials, C-BEYOND in the US and Canada which is currently enrolling patients, and C-FORWARD, a global trial outside of North America which is expected to begin enrollment of patients in Q2 2025. Each Phase 3 trial will enroll approximately 880 treatment-naïve patients, including those with and without compensated cirrhosis. The trials will compare the fixed dose combination (FDC) regimen of bemnifosbuvir and ruzasvir to the FDC regimen of sofosbuvir and velpatasvir. The regimen of bemnifosbuvir and ruzasvir will be administered orally once-daily for 8 weeks (in patients without cirrhosis) or 12 weeks (in patients with compensated cirrhosis) while the regimen of sofosbuvir and velpatasvir will be administered orally once-daily for 12 weeks for all patients with or without compensated cirrhosis.

The primary endpoint for each trial is HCV RNA < lower limit of quantitation (LLOQ) at 24 weeks from the start of treatment and encompasses sustained virologic response 12 weeks post-treatment (SVR12) in each arm. Measurement at 24 weeks from the start of treatment is to ensure the primary endpoint occurs at the same relative timepoint from the start of treatment in all patients. While C-BEYOND and C-FORWARD are both open-label trials, Atea has put measures and processes in place that are designed to blind Atea personnel to patient treatment assignments.

The initiation of the Phase 3 program follows a successful engagement with the US Food and Drug Administration (FDA) at an End-of-Phase 2 meeting in January 2025, shortly after the Company announced that its Phase 2 study evaluating the potential best-in-class regimen of bemnifosbuvir and ruzasvir met its primary endpoints of safety and SVR12.

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 Bemnifosbuvir and Ruzasvir for 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. In both nonclinical and clinical studies, bemnifosbuvir has been shown to have a low risk for drug-drug interactions. Bemnifosbuvir 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 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 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 hepatitis C virus. 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 and the potential best in class profile of the regimen and the ability of the regimen, if approved, to help improve patient outcomes and to provide opportunities to expand the number of patients treated and cured. 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 regimen of bemnifosbuvir and ruzasvir for the treatment of HCV; 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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