Atea Pharmaceuticals Announces Dosing of First Patient in C-BEYOND, Phase 3 Study Evaluating Regimen of Bemnifosbuvir and Ruzasvir for Treatment of Hepatitis C Virus

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Regimen has Potential Best-in-Class Profile with Short Treatment Duration, Low Risk for Drug-Drug Interactions and Convenience with No Food Effect

HCV Infection Remains a Significant Global Health Burden, with Approximately 50 Million People Infected, Including up to 4 Million in US

New Next-Generation HCV Therapies are Needed to Improve Patient Outcomes

BOSTON, April 09, 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 first patient has been dosed in C-BEYOND, Atea's Phase 3 trial evaluating the regimen of bemnifosbuvir and ruzasvir for the treatment of adults with chronic hepatitis C virus (HCV). C-BEYOND is an open-label trial being conducted in the US and Canada comparing the combination regimen of bemnifosbuvir and ruzasvir to the combination 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.

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.

"Dosing the first patient in our global Phase 3 program is a major advancement as we work to deliver a differentiated, next-generation therapy for HCV," said Jean-Pierre Sommadossi, PhD, Chief Executive Officer and founder of Atea. "The unrelenting high rate of HCV infections in the US is outpacing treatment rates and underscores the need for a new therapy that better addresses the current needs of both patients and prescribers. Untreated chronic HCV can have a profound impact on patients' lives, as well as the associated healthcare hospitalization costs, as the disease progresses. We believe our regimen, which combines key features of short treatment duration, low risk for drug-drug interactions, and convenience with no food effect, if successfully developed, has best-in-class potential and the opportunity to improve patient outcomes and to expand the number of patients treated."

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

Atea is conducting two open-label Phase 3 trials, C-BEYOND in the US and Canada, and C-FORWARD, a global trial outside of North America. 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 HCV

HCV is a blood-borne, positive-sense, single-stranded (ss) RNA virus that primarily infects liver cells. A leading cause of chronic liver disease and liver transplants, HCV is mainly spread via blood transfusion, hemodialysis and needle sticks, with 242,000 deaths occurring each year. Chronic HCV infection is the leading cause of liver cancer in the US, Europe and Japan.

In the US, HCV infections predominate in patients in the age group between 20-49 years old, and it is estimated that fewer than 10% of patients have cirrhosis.

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. 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.

Contacts

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

Joyce Allaire
LifeSci Advisors
Jallaire@lifesciadvisors.com