Atea Pharmaceuticals Announces Continued Advancement of Global Phase 3 HCV Program with Dosing of First Patient in C-FORWARD Outside North America

June 24, 2025

C-FORWARD is the Second Phase 3 Trial in the Global HCV Development Program; the First Phase 3 Trial, C-BEYOND, is Currently Enrolling Patients in the US and Canada

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

BOSTON, June 24, 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 was dosed in the global Phase 3 C-FORWARD trial evaluating the combination regimen of bemnifosbuvir and ruzasvir compared to the regimen of sofosbuvir and velpatasvir for the treatment of hepatitis C virus (HCV). C-FORWARD, the second of two Phase 3 trials comparing this regimen, is being conducted at study sites outside of North America. Atea initiated C-BEYOND, the Company's Phase 3 trial in the US and Canada in April 2025 and continues to enroll patients in that study. In both studies, the regimen of bemnifosbuvir and ruzasvir is being 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 is being administered orally once-daily for 12 weeks.

“We are pleased to reach another important milestone for our global HCV program with the first patient dosed in C-FORWARD, our HCV Phase 3 trial being conducted outside North America. Our Phase 3 program is now enrolling patients on a global basis,” said Jean-Pierre Sommadossi, PhD, Chief Executive Officer and founder of Atea. “We are focused on the successful development of a potential best-in-class HCV regimen that may make it easier to treat and cure patients infected with HCV. The target profile of our regimen is particularly well suited for both patients and healthcare providers in test-to-treat models of care, which enables seamless diagnosis and treatment for patients infected with HCV.”

HCV continues to be a significant global health burden despite the availability of direct-acting antivirals, with an estimated 50 million people worldwide chronically infected with HCV, and approximately one million new infections each year. It is estimated that between 2.4 to 4 million people in the US alone are living with chronic HCV.

“It has been nearly a decade since the last generation of treatments for HCV became available to patients and in this time, the patient population and what they need to obtain a cure has evolved. Many patients infected with HCV are taking concomitant medications, including some that may not be recommended with the currently available HCV therapies,” said Dr. Eric Lawitz, MD, The Texas Liver Institute, Clinical Professor of Medicine, University of Texas Health San Antonio. “The regimen of bemnifosbuvir and ruzasvir may offer a potent and more convenient option for my patients and may also make treatment more accessible for any patient who tests positive for HCV. I look forward to seeing the Phase 3 results when they are available.”

“The evolving HCV patient population and rising burden of untreated HCV in Europe mirrors trends seen in North America. Many patients present with co-morbidities and complex medical histories, with treatment decisions often influenced by concomitant medications,” said Tarik Asselah, MD, PhD, a principal investigator in the C-FORWARD trial and a Professor of Hepatology, Hôpital Beaujon, Assistance Publique–Hôpitaux de Paris (AP-HP), University of Paris-Cité, France. “To truly advance HCV eradication and meet the needs of today’s patients, an ideal treatment would combine high efficacy, short duration, and minimal risk of drug-drug interactions."

Atea hosted a virtual HCV panel discussion with key opinion leaders (KOLs) on May 14, 2025. A panel of six experts, including leading hepatologists and prescribers from the US, Canada and Europe, discussed the current challenges for patients infected with HCV and the results from Atea’s global Phase 2 study evaluating the regimen of bemnifosbuvir, a nucleotide analog polymerase inhibitor, and ruzasvir, an NS5A inhibitor were reviewed. Company management also reviewed the HCV commercial market opportunity and the design for the global Phase 3 clinical development program. To listen to the replay of the KOL event, please click here.

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 is expected to enroll approximately 880 treatment-naïve patients, including those with and without compensated cirrhosis. The trials are comparing the fixed dose combination (FDC) regimen of bemnifosbuvir and ruzasvir to the FDC regimen of sofosbuvir and velpatasvir. The regimen of bemnifosbuvir and ruzasvir is being 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 is being 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.

Last month, at the European Association for the Study of the Liver (EASL) Congress 2025, Atea presented results from the full cohort of patients (n=275) enrolled in its Phase 2 study evaluating the regimen. These results showed a robust 98% (210/215) SVR12 with the regimen in the

“Per-Protocol Treatment-Adherent Population.” The SVR12 rate was 95% (245/259) in the “Per-Protocol Regardless of Adherence Population” (also referred to as the “efficacy evaluable population”), which included patients who were not treatment adherent (17%).

Results from three additional Phase 1 studies demonstrated that the combination of bemnifosbuvir and ruzasvir had a low risk of drug-drug interactions (DDIs) and supported the safety of the regimen in HCV patients co-infected with human immunodeficiency virus (HIV) taking a standard HIV treatment, and the safety of bemnifosbuvir in participants with hepatic or renal impairment with no need for dose adjustments.

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 approximately 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 DDIs. 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 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. Atea’s lead program and current focus is on the development of the combination 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 Statement

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 potential best-in-class profile of the regimen of bemnifosbuvir and ruzasvir for the treatment of HCV and the potential to develop a regimen that makes it easier to treat and cure HCV patients. 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, uncertainties inherent in the drug discovery and development process and the regulatory submission or approval process, unexpected or unfavorable safety or efficacy data or results observed during clinical trials or in data readouts; delays in or disruptions to clinical trials or our business; our reliance on third parties over which we may not always have full control, our ability to manufacture sufficient commercial product, competition from approved treatments for HCV, 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 HCV; as well as the other important factors discussed under the caption “Risk Factors” in Atea’s Quarterly Report on Form 10-Q for the quarter ended March 31, 2025 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