Atea Pharmaceuticals Completes Patient Enrollment in North American Phase 3 Trial Evaluating Regimen of Bemnifosbuvir and Ruzasvir for Treatment of Hepatitis C Virus

December 22, 2025

Enrollment Completed in C-BEYOND Phase 3 Trial with More Than 880 HCV Treatment-Naïve Patients in US and Canada

C-BEYOND Topline Results Expected Mid-2026

C-FORWARD Phase 3 Trial, Conducted Outside North America, Enrollment Completion Expected Mid-2026 with Topline Results Anticipated Year-End 2026

C-BEYOND AND C-FORWARD are the First Global Phase 3 Head-to-Head Trials of Direct-Acting Antivirals for Treatment of HCV

BOSTON, Dec. 22, 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 completion of enrollment of more than 880 treatment-naïve patients in the C-BEYOND Phase 3 trial evaluating the fixed-dose combination (FDC) regimen of bemnifosbuvir and ruzasvir compared to the FDC regimen of sofosbuvir and velpatasvir for the treatment of hepatitis C virus (HCV). C-BEYOND is being conducted at approximately 120 clinical trial sites in the US and Canada. Phase 3 topline results are expected mid-year 2026.

In addition to C-BEYOND, Atea continues to advance enrollment of treatment-naïve patients in C-FORWARD, a Phase 3 trial evaluating this same FDC regimen in 880 patients at approximately 120 clinical trial sites in up to 17 countries outside of North America. Completion of enrollment in C-FORWARD is expected mid-year 2026, with Phase 3 topline results anticipated year-end 2026. In both studies, the FDC regimen of bemnifosbuvir and ruzasvir is administered orally once-daily for 8 weeks (in patients without cirrhosis) or 12 weeks (in patients with compensated cirrhosis) while the comparator FDC regimen of sofosbuvir and velpatasvir is administered orally once-daily for 12 weeks.

“Completing enrollment in C-BEYOND marks a critical inflection point in our Phase 3 HCV program and we are on track to deliver topline results from this trial mid-2026,” said Jean-Pierre Sommadossi, PhD, Chief Executive Officer and Founder of Atea. “Our goal is and has always been to develop a best-in-class HCV treatment that meaningfully advances the standard of care. We believe that the target profile of our regimen — featuring short treatment duration, low risk of drug-drug interactions and convenience with no food effect — will uniquely position us to address the evolving needs of today’s patients and bring us closer to the ultimate goal of HCV eradication.”

HCV continues to be a significant global health burden despite the availability of direct-acting antivirals (DAAs). Up to 4 million people in the US are living with chronic HCV, and an estimated 50 million people are infected worldwide with approximately one million new infections occurring each year. In the US, HCV diagnoses continue to outpace annual cure rates. According to healthcare providers who treat patients with HCV, approximately 80 percent of HCV patients take multiple medications to manage comorbidities and coinfections and concerns related to currently approved HCV therapeutics and drug-drug interactions are a significant factor in HCV treatment delay. As a result, a new treatment option offering high efficacy, short treatment duration, and a low risk of drug-drug interactions could meaningfully help to address patient needs and further the goal of HCV eradication.

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

Atea’s HCV development program includes two open-label Phase 3 trials, C-BEYOND conducted in the US and Canada, and C-FORWARD conducted outside of North America. Each trial is enrolling approximately 880 treatment-naïve patients, including those with or without compensated cirrhosis. The trials compare the FDC regimen of bemnifosbuvir, a nucleotide analog polymerase inhibitor, and ruzasvir an NS5A inhibitor, to the FDC regimen of sofosbuvir and velpatasvir. The regimen of bemnifosbuvir and ruzasvir is administered orally once-daily for eight weeks (in patients without cirrhosis) or 12 weeks (in patients with compensated cirrhosis) while the regimen of sofosbuvir and velpatasvir is administered orally once-daily for 12 weeks to 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.

About 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 approximately 240,000 deaths occurring each year. Despite the availability of DAAs, 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, up to 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. Atea's lead program is 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 potential best-in-class profile of the bemnifosbuvir/ruzasvir regimen for the treatment of HCV, the potential opportunity to advance efforts to eradicate HCV, future results of operations and financial position, business strategy, anticipated milestone events and timelines for clinical trials, benefits of cost savings initiatives, repurchases under the Company's share repurchase program, and the timing and outcome of the Company's strategic alternatives review. 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 bemnifosbuvir/ruzasvir regimen 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 September 30, 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