Atea Pharmaceuticals Meets Both Its Primary and Secondary Endpoints in the Phase 3 C-BEYOND North America Trial Evaluating Bemnifosbuvir/Ruzasvir for Hepatitis C Virus

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Bemnifosbuvir/Ruzasvir (BEM/RZR) Achieved its Primary Endpoint of Statistical Non-inferiority Compared to Sofosbuvir/Velpatasvir (SOF/VEL; Epclusa®), a Standard-of-Care, in First-Ever Successful Head-to-Head Trial in a Global Phase 3 Program of Hepatitis C Virus (HCV) Treatments

Results Reinforce Potential Best-in-Class Profile of BEM/RZR as a Short 8-Week Treatment for Patients Without Cirrhosis

Up to 4 Million People in the US Living with HCV, Which Can Progress to Cirrhosis, End-Stage Liver Disease and Liver Cancer if Left Untreated

BOSTON, July 28, 2026 (GLOBE NEWSWIRE) -- Atea Pharmaceuticals, Inc. (Nasdaq: AVIR) (Atea or Company), a late-stage clinical biopharmaceutical company developing oral antiviral therapeutics for serious viral diseases, today announced positive topline results from C-BEYOND, its pivotal Phase 3 trial conducted in North America evaluating the once-daily fixed-dose combination of bemnifosbuvir and ruzasvir (BEM/RZR) for the treatment of chronic hepatitis C virus (HCV) infection. BEM/RZR demonstrated statistical non-inferiority compared to the fixed-dose combination of sofosbuvir and velpatasvir (SOF/VEL) in the modified intent-to-treat (mITT) population, achieving the trial's primary endpoint. C-BEYOND enrolled patients reflective of the current real-world population living with HCV in the US and Canada.

In the mITT analysis (n=905, cirrhotic and non-cirrhotic), BEM/RZR achieved a 93.9% sustained virologic response (SVR) rate vs. 94.8% for SOF/VEL (Epclusa) at Week 24, encompassing SVR at 12 weeks post-treatment (accepted definition of cure for HCV) in both arms. These results achieved the primary endpoint of statistical non-inferiority, with a 95% confidence interval for difference in SVR rates within the prespecified 5% margin. The mITT analysis in patients without cirrhosis (n=721) showed BEM/RZR (8 weeks of treatment) achieved a 93.5% SVR rate vs. 94.6% for SOF/VEL (12 weeks of treatment). In patients with cirrhosis (12 weeks treatment in both arms) (n=184), BEM/RZR achieved a 95.4% SVR rate vs. 95.4% for SOF/VEL. In C-BEYOND, rates of virologic failure across all populations were low and comparable between treatment arms. Statistical non-inferiority was also met in secondary endpoints, including the per-protocol analysis.

"We are pleased to announce these positive results from C-BEYOND showing our regimen of BEM/RZR achieved high cure rates across all populations and genotypes," said Jean-Pierre Sommadossi, PhD, Founder and Chief Executive Officer of Atea Pharmaceuticals. "As today is World Hepatitis Day, it underscores that HCV presents complex public health challenges. We believe the profile of our regimen will substantially contribute to the World Health Organization's goal of HCV eradication. We look forward to sharing results from C-FORWARD, Atea's second Phase 3 trial of BEM/RZR outside North America, in early 2027, and to bringing BEM/RZR to patients as soon as possible."

"Achieving these high cure rates with just 8 weeks of BEM/RZR in patients without cirrhosis, alongside a favorable drug-drug interaction profile and the flexibility to be taken with or without food, is a meaningful step forward for HCV care. A shorter, simpler regimen has the potential to streamline prescribing decisions and accelerate the test-and-treat strategies that are essential to HCV elimination," said Eric Lawitz, MD, Clinical Professor of Medicine at UT Health San Antonio and the Texas Liver Institute. "Many of the patients I see in my practice are managing multiple chronic conditions, taking several concomitant medications, and navigating real barriers to consistent follow-up. Those realities are exactly why we need HCV regimens that are highly effective, convenient to administer and compatible with the medications patients are already taking every day."

BEM/RZR was administered as an 8-week regimen to patients without cirrhosis compared with the 12-week regimen of SOF/VEL, highlighting the potential of BEM/RZR to deliver robust antiviral efficacy with a shorter treatment duration. In the US, approximately 80-90% of people living with HCV do not have cirrhosis. Together with its potential advantages of a shorter treatment duration for most patients, low risk of drug-drug interactions and no food effect, the results from C-BEYOND further reinforce BEM/RZR's potential as a differentiated, best-in-class treatment option for people with HCV.

Chronic HCV infection remains an ongoing public health crisis. If left untreated, HCV can progress to cirrhosis, end-stage liver disease and liver cancer, and it remains one of the leading causes of liver cancer in the US, Europe and Japan. Approximately 50 million people worldwide are living with HCV, including up to 4 million people in the US, while new diagnoses continue to outpace annual cures. Additionally, many people living with HCV are also managing other chronic conditions, and roughly 80% take multiple concomitant medications for common comorbidities such as heartburn, heart arrhythmia, high blood pressure and gastroesophageal reflux disease (GERD), which may increase the potential for drug-drug interactions with currently approved therapies.

In C-BEYOND, BEM/RZR demonstrated robust SVR rates across HCV genotypes that predominate in North America. C-FORWARD, which is being conducted outside North America, includes a broader range of HCV genotypes and is expected to provide additional efficacy data in genotypes more frequently found outside the US and Canada. In C-BEYOND, BEM/RZR was generally safe and well tolerated with no drug-related serious adverse events or drug related early treatment discontinuations. Safety was comparable between treatment arms.

"We are grateful to the patients and clinicians who participated in the C-BEYOND study, whose engagement and support made this important progress possible in the first-ever successful head-to-head trial in a global Phase 3 HCV program," said Janet Hammond, MD, PhD, Chief Development Officer of Atea Pharmaceuticals. "These strong results underscore the promise of BEM/RZR for the treatment of patients infected with HCV. Looking ahead, we believe C-FORWARD will provide important additional insight into the regimen's efficacy across HCV genotypes which are less common in the US and Canada, and further our goal of bringing a simplified, effective HCV treatment option to patients worldwide."

C-BEYOND was conducted at approximately 120 sites in the US and Canada. C-FORWARD, which is fully enrolled with more than 880 patients, is being conducted at approximately 120 sites in 17 countries outside North America and is on track to report topline results in early 2027. Atea plans to

present the detailed results of its global Phase 3 program in HCV at future medical conferences and submit to peer-reviewed medical journals for publication.

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

The global Phase 3 program is evaluating the fixed-dose combination (FDC) of BEM/RZR for the treatment of chronic HCV in patients with and without compensated cirrhosis. The program consists of two open-label controlled trials: C-BEYOND in North America and C-FORWARD outside North America. C-BEYOND (NCT06868264) enrolled 905 (mITT population) treatment-naïve patients, while C-FORWARD (NCT07037277) has enrolled more than 880 treatment-naïve patients. The trials compare the FDC regimen of BEM, a nucleotide analog polymerase inhibitor, and RZR, an NS5A inhibitor, to the FDC regimen of SOF/VEL. The regimen of BEM/RZR is administered orally once daily for eight weeks (in patients without cirrhosis) or 12 weeks (in patients with compensated cirrhosis), while the regimen of SOF/VEL 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 below the 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. SVR12 is the accepted definition of cure for HCV. Measurement at 24 weeks from the start of treatment is to ensure the primary endpoint measurement occurs at the same relative timepoint from the start of treatment in all patients. The primary endpoint was assessed in the mITT population in C-BEYOND, which is comprised of all patients who received at least one dose of the regimen and includes patients who discontinued early, were not compliant or were lost to follow-up. The mITT analysis is the agreed upon primary endpoint with the United States Food and Drug Administration (FDA).

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 pharmacokinetic (PK) profile of BEM 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 3,200 subjects and has been well-tolerated at doses up to 550 mg for durations up to 12 weeks in healthy subjects and patients.

RZR has demonstrated highly potent and pan-genotypic antiviral activity in preclinical (picomolar range) and clinical studies. RZR has been administered to over 3,100 HCV-infected patients at daily doses of up to 180 mg for 12 weeks and has demonstrated a favorable safety profile. The PK profile of RZR supports once-daily dosing.

About HCV

HCV is a blood-borne, single-stranded (ss) RNA virus that primarily infects liver cells. HCV is a leading cause of chronic liver disease and liver transplants and can be spread through blood transfusion, hemodialysis and needle sticks, with approximately 240,000 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, approximately four million people are estimated to have HCV with annual new infections outpacing treatment rates. HCV infections in the US predominate among patients between 20 and 49 years old, and it is estimated that approximately 80-90% of people living with HCV in the US do not have cirrhosis. Chronic HCV infection is the leading cause of liver cancer in the US, Europe and Japan.

About Atea Pharmaceuticals

Atea is a late-stage clinical 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 Phase 3 program is evaluating the FDC regimen of BEM, a nucleotide analog polymerase inhibitor, and RZR, an NS5A inhibitor, to treat HCV. Atea is also currently conducting a Phase 1 clinical study of AT-587, a nucleotide analog, for the treatment of HEV. 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 regimen of BEM/RZR for the treatment of HCV and anticipated milestone events including the timeline for readout of the C-FORWARD Phase 3 clinical trials results. When used herein, words including "potential," "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 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; dependence on the success of Atea's most advanced product candidates, in particular the BEM/RZR 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 March 31, 2026 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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