Atea Pharmaceuticals Presents New Data Supporting the Fixed-Dose Combination of Bemnifosbuvir and Ruzasvir as a Potential Best-in-Class Regimen for Treatment of Hepatitis C Virus Infection at The Liver Meeting® 2025

November 7, 2025

Company Hosting Virtual KOL Panel Event Thursday, November 13th at 10:00 AM ET

BOSTON, Nov. 07, 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 the presentation of new modeling data predicting that the Company's combination regimen of bemnifosbuvir (BEM), a nucleotide analog polymerase inhibitor, and ruzasvir (RZR), an NS5A inhibitor, achieved near-complete inhibition of both viral replication and assembly and secretion into the bloodstream, with a modeled time to cure of approximately 7 to 8 weeks. These findings support the fixed-dose combination (FDC) regimen of BEM and RZR as a potential best-in-class, convenient, short-duration treatment of hepatitis C virus (HCV), further validating the Company's Phase 2 study results, which demonstrated that the combination regimen, after 8 weeks of treatment, achieved sustained virologic response rates at 12 weeks post-treatment (SVR12) of 98% in the per-protocol treatment-adherent patient population and 95% in patients regardless of adherence. These modeling data will be presented at The Liver Meeting® 2025, the annual meeting of the American Association for the Study of Liver Diseases (AASLD), taking place November 7-11 in Washington, DC.

The Company will also present two additional datasets: 1) a resistance analysis from the same Phase 2 study supporting the regimen's high barrier to resistance and 2) results from a Phase 1 study in healthy participants demonstrating the high relative bioavailability of the BEM/RZR FDC commercial formulation. These data also support dosing of the FDC with or without food or with famotidine (an H2 blocker which can substantially diminish the effectiveness of HCV oral antivirals). The FDC commercial formulation is being used in the ongoing Phase 3 program.

All results being presented underscore the regimen's potential best-in-class profile to address the needs of today's broad population of HCV patients. This includes those patients taking concomitant medications, who may need the flexibility of a treatment option that can be taken with or without food, or who present with resistant strains of HCV or advanced liver disease.

"Our goal has always been to develop a best-in-class regimen for HCV that meaningfully advances the standard of care for as many people as possible by addressing the evolving needs of today's HCV patients," said Jean-Pierre Sommadossi, PhD, Chief Executive Officer and Founder of Atea Pharmaceuticals. "These new findings reinforce the differentiated profile of our fixed-dose combination regimen of bemnifosbuvir and ruzasvir as a potent, pan-genotypic and convenient regimen with the potential to transform the treatment landscape and bring us closer to eradication of HCV."

Despite the availability of direct-acting antiviral therapies, HCV remains a significant public healthcare crisis in the US and globally with new diagnoses continuing to outpace cure rates. With a significant portion of the HCV patient population navigating co-infections or taking concomitant medications, an optimized, next-generation treatment option is needed to address their needs and meaningfully advance HCV eradication.

Summary of Results Being Presented at AASLD The Liver Meeting:

Oral Presentation

Abstract Number: 0089
Title: Multiscale Modeling of Results from a Phase 2 Study of an 8-week Combination Regimen of Bemnifosbuvir and Ruzasvir in Patients with Chronic Hepatitis C Virus Infection
Date and Time: Monday, November 10th, 11:30 AM – 11:45 AM ET
Presenting Author: Carolin Zitzmann, PhD
Conclusion: Multiscale modeling data show that Atea's combination regimen of BEM and RZR inhibits both intracellular replication of HCV, as well as viral assembly and secretion of new HCV into the bloodstream in patients with chronic HCV infection with a modeled time to cure of approximately 7 to 8 weeks. Because the regimen suppresses the virus at multiple critical stages, the data support the potential of the combination regimen as a simplified, short-duration therapy for chronic HCV.

Poster Presentations

Abstract Number: 1381
Identified as a Poster of Distinction
Title: No Impact of RASs on the High Efficacy of BEM and RZR in Combination: Resistance Analysis from a Phase 2 Study in HCV-Infected Patients
Date and Time: Friday, November 7th, 8:00 AM – 5:00 PM ET
Presenting Author: Qi Huang, PhD
Conclusion: A resistance analysis from the Company's Phase 2 study of BEM and RZR demonstrated that SVR12 rates were not impacted by resistance associated substitutions (RASs). These data support the regimen's high barrier to resistance in patients infected with HCV. Viral kinetic and pharmacokinetic analyses indicated that most of the viral failures were due to treatment non-adherence.

Abstract Number: 1398

Title: Bemnifosbuvir and Ruzasvir Provided as a Fixed-dose Combination (FDC) Demonstrates High Relative Bioavailability to Their Individual Formulations and Can Be Dosed with No Regard to Food

Date and Time: Friday, November 7th, 8:00 AM – 5:00 PM ET

Presenting Author: Xiao-Jian Zhou, PhD

Conclusion: Results from a Phase 1 study in healthy participants demonstrated the high relative bioavailability of the BEM and RZR FDC commercial formulation. These results also support dosing of the FDC with or without food or with famotidine (an H2 blocker which can substantially diminish the effectiveness of HCV oral antivirals). The FDC commercial formulation is being used in the ongoing Phase 3 program.

HCV KOL Investor Event at 10:00 AM ET on November 13, 2025

Following The Liver Meeting 2025, Atea will host a virtual event for investors with a panel of leading HCV clinical experts on Thursday, November 13 at 10:00 AM ET. To register, click here.

The panel will include global leaders in hepatology and HCV research and treatment, including:

- **Jordan Feld, MD, MPH –** University of Toronto, Toronto General Hospital, Canada
- **Eric Lawitz, MD –** Texas Liver Institute, University of Texas Health San Antonio, US
- **Anthony Martinez, MD –** University of Buffalo, Erie County Medical Center, US
- **Nancy Reau, MD –** Rush University Medical Center, Chicago, US

These experts will discuss the current challenges patients and prescribers face in the diagnosis and treatment of HCV, strategies for advancing global HCV eradication efforts and the potential benefits a next-generation treatment option with an optimized profile could provide for prescribers and HCV patients.

Company management will discuss the HCV commercial market opportunity and provide an update on the ongoing global Phase 3 clinical development program, followed by a live Q&A session.

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

Atea's HCV Phase 3 development program includes two open-label Phase 3 trials, C-BEYOND being conducted in the US and Canada, and C-FORWARD being conducted outside of North America. Each Phase 3 trial is enrolling approximately 880 treatment-naïve patients, including those with or without compensated cirrhosis. The trials 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 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 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 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, between 2.4 and 4.0 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

Results from the Phase 2 study (n=275) evaluating the regimen of bemnifosbuvir and ruzasvir for 8 weeks showed a 98% SVR12 rate (210/215) 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 Phase 1 studies have demonstrated that the combination of bemnifosbuvir and ruzasvir has a low risk of drug-drug interactions (DDIs) and can be taken with or without food. Importantly, Phase 1 results showed no interaction between bemnifosbuvir and ruzasvir and a standard human immunodeficiency virus (HIV) treatment, supporting its potential use in HCV patients co-infected with HIV, and the safety of bemnifosbuvir in healthy volunteer participants with hepatic or renal impairment with no need for dose adjustments.

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. 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.

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 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 transform the HCV landscape and advance potential eradication of HCV. 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 discussed under the caption "Risk Factors" in Atea's Quarterly Report on Form 10-Q for the period ended June 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.. 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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