Atea Pharmaceuticals Announces Full Results from Phase 2 Study of Regimen of Bemnifosbuvir and Ruzasvir for Treatment of Hepatitis C Virus (HCV) Presented at EASL Congress 2025

May 7, 2025

Full Results from Phase 2 Study Confirmed 98% Sustained Virologic Response at 12 Weeks Post-Treatment (SVR12) After Short 8-Week Treatment Duration for Regimen

Results from Phase 1 Study Showed Low Risk for Drug-Drug Interactions with Regimen When Co-Administered with Standard HIV Treatment Regimen

Bemnifosbuvir Was Generally Safe and Well Tolerated with No Dose Adjustment Needed in Phase 1 Studies in Participants with Hepatic or Renal Impairment

Atea Pharmaceuticals to Host Virtual HCV KOL Panel on May 14, 2025

BOSTON, Mass., May 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 presented results from the full cohort of patients (n=275) enrolled in its Phase 2 study evaluating the once-daily combination of bemnifosbuvir (BEM), an oral nucleotide NS5B polymerase inhibitor, and ruzasvir (RZR), an oral NS5A inhibitor, for the treatment of hepatitis C virus (HCV). The Phase 2 study met its primary endpoints of efficacy and safety. With a short 8-week treatment duration, the Phase 2 results showed a robust 98% (210/215) sustained virologic response rate at 12 weeks post-treatment (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 BEM/RZR had a low risk of drug-drug interactions (DDIs) and supported the safety of the regimen of BEM/RZR in patients co-infected with HCV and human immunodeficiency virus (HIV) taking a standard HIV treatment, and the safety of BEM in participants with hepatic or renal impairment with no need for dose adjustments.

These results were presented at the European Association for the Study of the Liver (EASL) Congress 2025 from May 7-10 in Amsterdam, Netherlands.

"The full results from the Phase 2 trial highlight the potential for our regimen to optimize the treatment of hepatitis C virus in all patients," said Jean-Pierre Sommadossi, PhD, Chief Executive Officer and Founder of Atea Pharmaceuticals. "Our potential best-in-class regimen, which has attributes of a short treatment duration, low risk for drug-drug interactions and convenience with no food effect, creates new opportunities to treat and cure an expanded number of HCV-infected patients, and we are eager to further explore these benefits in our C-BEYOND and C-FORWARD Phase 3 trials."

The Phase 2 study was conducted in treatment-naïve, chronic HCV-infected patients across genotypes either without cirrhosis (n=238) or with compensated cirrhosis (n=37). Results demonstrated 99% of treatment-adherent patients who were non-cirrhotic and infected with genotypes 1-4 achieved SVR12, demonstrating robust pan-genotypic potency and supporting an 8-week treatment duration in non-cirrhotic patients in the Phase 3 program. A 100% SVR12 rate was observed in non-cirrhotic, treatment-adherent patients infected with genotype 3, a historically difficult genotype to treat and cure.

"The average HCV patient we are treating today is quite different than several years ago – patients are more recently infected with fewer presenting with cirrhosis, and the majority are taking concomitant medications, including some that may not be recommended with the currently available HCV therapies,” said Eric Lawitz, MD, The Texas Liver Institute, Clinical Professor of Medicine, University of Texas Health San Antonio. “I am encouraged by the complete Phase 2 results suggesting that the regimen of bemnifosbuvir and ruzasvir may offer a potent and more convenient option for my patients. I look forward to seeing the Phase 3 results when they are available.”

Compensated cirrhosis was present in 13.5% (n=37) of the study participants and the SVR12 rate was 88% (30/34) in those who were treatment-adherent. Although viral kinetics were slower among patients with cirrhosis, all achieved HCV RNA <LLOQ by the end of treatment (at week 8), suggesting that a 12-week treatment duration will maximize efficacy in this population. Furthermore, exploratory viral kinetic modeling supported time-to-cure estimates of 12 weeks in those with compensated cirrhosis.

Between 2.4 to 4.0 million people in the US are living with chronic HCV, and an estimated 50 million people are infected worldwide. In the US, HCV diagnoses continually outpace cure rates annually. Today, as many as 80 percent of patients infected with HCV are taking concomitant medications[1], creating a persistent need for a treatment option with robust potency, limited drug-drug interactions and a strong drug forgiveness profile.

Summary of Results Presented at EASL

Poster Title: Efficacy and Safety of Bemnifosbuvir and Ruzasvir after 8 Weeks of Treatment in Patients with Chronic Hepatitis C Virus (HCV) Infection (TOP-251)
Conclusion: The Phase 2 study results demonstrated that an 8-week combination regimen BEM (550 mg) and RZR (180 mg) achieved SVR12 in 98% of treatment-adherent patients and 95% of patients regardless of treatment adherence. Among patients with compensated cirrhosis, SVR12 was

88%, with all individuals reaching undetectable viral levels at the end of the 8-week treatment regimen. The regimen was safe and well-tolerated with low rates of virologic failure and no study-drug-related serious adverse events or treatment discontinuations. Treatment emergent adverse events (TEAEs) were reported in 43% (118/275) of patients. Most TEAEs were mild to moderate in intensity, with headache (9%) and nausea (8%) being the most reported. These results reinforce the potential of the combination regimen of bemnifosbuvir and ruzasvir as a best-in-class treatment for HCV.

Poster Title: Pharmacokinetics of Bemnifosbuvir in Participants with Hepatic Impairment (WED-278)
Conclusion: A Phase 1 pharmacokinetic study evaluating a single 550 mg dose of BEM in participants with varying degrees of hepatic impairment showed increased drug exposure in individuals with moderate to severe liver dysfunction. However, these changes did not meaningfully affect levels of AT-273, the plasma marker for the active intracellular antiviral metabolite of BEM. No safety concerns were identified. These results support the use of BEM without dose adjustment in patients with hepatic impairment.

Poster Title: No DDI Between Bemnifosbuvir/Ruzasvir and Bictegravir/Emtricitabine/Tenofovir Alafenamide (WED-279)
Conclusion: Findings from a Phase 1 drug-drug interaction study in healthy participants demonstrated that co-administration of BEM/RZR with the standard human immunodeficiency virus (HIV) regimen bictegravir/emtricitabine/tenofovir alafenamide (B/FTC/TAF) resulted in no clinically significant pharmacokinetic changes. The co-administered HCV/HIV combinations were generally safe and well tolerated. These results support the future inclusion of HCV/HIV co-infected patients receiving these HIV therapies in the Phase 3 clinical development program for BEM/RZR.

It is estimated that in the US as many as 6 to 30% of HCV patients are co-infected with HIV.[2]

Poster Title: Pharmacokinetics of Bemnifosbuvir in Participants with Renal Impairment (WED-280)
Conclusion: A Phase 1 renal impairment study showed that a single 550 mg dose of BEM was safe and well-tolerated across participants with normal kidney function, moderate-to-severe renal impairment, and those with end-stage renal disease on hemodialysis. While the circulating inactive nucleoside metabolites of BEM increased as expected in renally impaired individuals, exposure of BEM remained consistent. These findings suggest that BEM may be used without dose adjustment in patients with renal dysfunction, including those undergoing dialysis.

HCV KOL Investor Event at 10:00 AM ET on May 14, 2025

Following the EASL Congress 2025, Atea will host a virtual key opinion leader (KOL) investor event with a panel of HCV experts and prescribers on Wednesday, May 14, 2025, at 10:00 AM ET. To register, click here.

This event will include several US and ex-US physicians who are leaders in hepatology, gastroenterology, infectious diseases, and HCV treatments. These experts and prescribers will discuss the current challenges encountered by patients with HCV, the full results from Atea's global Phase 2 study evaluating the regimen of BEM/RZR for the treatment of HCV, and what a new optimized HCV therapy could provide for prescribers and patients. Company management will discuss the HCV commercial market opportunity and the ongoing global Phase 3 clinical development.

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 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 to 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 the Bemnifosbuvir / Ruzasvir HCV Phase 3 Program

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 BEM/RZR to the FDC regimen of sofosbuvir and velpatasvir. The regimen of BEM/RZR will be 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 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. Patient enrollment in the C-BEYOND trial is ongoing and enrollment in the C-FORWARD trial is expected to begin mid-2025.

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 the topline results and that the Phase 2 study evaluating the potential best-in-class regimen of BEM/RZR met its primary endpoints of efficacy (SVR12) and safety.

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 BEM and RZR 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 and cured. 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

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[1] Atea Custom Market Research, IQVIA 2024, Atea clinical/in vitro DDI data

[2] https://clinicalinfo.hiv.gov/en/guidelines/hiv-clinical-guidelines-adult-and-adolescent-opportunistic-infections/hepatitis-c-virus#:~:text=Estimates%20of%20HCV%20coinfection%20in,of%20HIV%20transmission%20risk%20factors.&text=In%20the%20United%20States%2C%20it,HIV%20also%20have%20HCV%20infection