Atea Pharmaceuticals to Highlight 2025 Strategic Priorities at the 43rd Annual J.P. Morgan Healthcare Conference

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Global Phase 3 HCV Program Expected to Initiate in 1Q 2025

Potential Best-in-Class Profile of Bemnifosbuvir + Ruzasvir Regimen Supports Opportunity to Disrupt and Expand Global HCV Market of Approximately $3 Billion in Annual Net Sales

The Regimen, if Approved, Should Play an Important Role in Efforts to Reduce the Continuing High Disease Burden of HCV

BOSTON, Jan. 13, 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, will outline the Company's strategic priorities for 2025 at the 43rd Annual J.P. Morgan Healthcare Conference. Atea will present its plans for the regimen of bemnifosbuvir and ruzasvir, which the Company is advancing into a Phase 3 program for the treatment of Hepatitis C virus (HCV) and present data from market research studies supporting the commercial market opportunity. Further information can be found in the Company's presentation here. The Company also reports its cash, cash equivalents and marketable securities balance of $454.7 million at December 31, 2024 and a cash runway anticipated into 2028.

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 million people are estimated to have HCV with annual new infections outpacing treatment rates. Chronic HCV infection is the leading cause of liver cancer in the US, Europe and Japan.

"Atea has an exciting year ahead with our planned initiation of a global Phase 3 program for the regimen of bemnifosbuvir and ruzasvir for the treatment of HCV. Our potential best-in-class regimen offers drug potency and forgiveness with convenient, short treatment duration, low risk of drug-drug interactions and no food effect. Our US market research confirms that this profile provides a significant opportunity to address the large burden of untreated HCV disease and play a major role in the eradication of HCV," said Jean-Pierre Sommadossi, PhD, Chief Executive Officer and founder of Atea. "We believe our regimen, if approved, has the opportunity to disrupt the global HCV market of approximately $3 billion in annual net sales."

In recent surveys conducted for Atea, US healthcare providers report a high likelihood of prescribing the regimen of bemnifosbuvir and ruzasvir, if approved, and US payors are receptive to inclusion of the regimen on formulary based on its differentiated profile.[1]

Anticipated Global Phase 3 Program for HCV

In December 2024, Atea announced that its Phase 2 study evaluating the regimen of bemnifosbuvir, a nucleotide analog polymerase inhibitor, and ruzasvir, an NS5A inhibitor, for treatment of hepatitis C virus (HCV), met its primary endpoints. Based on these positive results, Atea has an End-of-Phase 2 meeting scheduled with the US Food and Drug Administration later this month to review the Phase 3 program. In the global Phase 3 program, Atea expects to conduct two open label Phase 3 trials, one in the US and Canada and one outside of North America. Each trial will enroll up to 800 treatment-naïve HCV patients, both with and without compensated cirrhosis. For non-cirrhotic patients, who comprise more than 90% of patients in the US, Atea expects to evaluate the efficacy of eight weeks of treatment in with the once-daily fixed dose tablet of bemnifosbuvir and ruzasvir versus 12 weeks of treatment with sofosbuvir/velpatasvir. For cirrhotic patients, 12 weeks of treatment with the once-daily fixed dose tablet of bemnifosbuvir and ruzasvir will be evaluated versus 12 weeks of treatment with sofosbuvir/velpatasvir. The primary endpoint is expected to be sustained virologic response at 12 weeks post-treatment (SVR12).

About the Phase 2 Study

The global Phase 2 study evaluating the regimen of bemnifosbuvir and ruzasvir for treatment of HCV met its primary endpoints of safety and SVR12. Primary endpoint results demonstrated a 98% (208/213) SVR12 rate in the per-protocol treatment adherent patient population after eight weeks of treatment with the regimen of bemnifosbuvir and ruzasvir. The efficacy evaluable patient population, which included 17% treatment non-adherent patients, achieved a 95% (242/256) SVR12 rate demonstrating the robust potency and forgiveness of the regimen. The regimen was generally safe and well-tolerated with no drug-related serious adverse events or treatment discontinuations. Full data from the Phase 2 study are anticipated to be presented at a scientific meeting during the first half of 2025.

The global Phase 2 study enrolled 275 treatment-naïve patients, both with and without compensated cirrhosis. The study was designed to evaluate the safety and efficacy of eight weeks of treatment with the regimen consisting of once-daily bemnifosbuvir 550 mg and ruzasvir 180 mg.

The primary endpoints of the study were safety and SVR12 in the per-protocol treatment adherent population. Secondary and other endpoints included SVR12 in the per-protocol population regardless of treatment adherence (efficacy evaluable), virologic failure and resistance.

About Bemnifosbuvir and Ruzasvir for Hepatitis C Virus (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 that 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. Bemnifosbuvir has been shown to have a low risk for drug-drug interactions. Bemnifosbuvir has been administered to over 2,200 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 1,500 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 ruzasvir supports once-daily dosing.

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 242,000 deaths occurring each year. Most HCV-related deaths are due to liver scarring (cirrhosis) and liver cancer (hepatocellular carcinoma). 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 the HCV infected patients in the US have cirrhosis.

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. Our 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 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 ability of the regimen, if approved, to disrupt and expand the global HCV market, reduce the continuing high disease burden and contribute to the 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, 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 combination of bemnifosbuvir and ruzasvir for the treatment of hepatitis C; 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, 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

Will O'Connor
Precision AQ
212-362-1200
will.oconnor@precisionaq.com

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[1] Atea Custom Research, PharmaValue Partners 2023 and Atea Custom Research, Formulary Insights 2024