Atea Pharmaceuticals Provides Update on Global Phase 3 SUNRISE-3 Trial Evaluating Bemnifosbuvir for Treatment of COVID-19

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BOSTON, Sept. 13, 2024 (GLOBE NEWSWIRE) -- Atea Pharmaceuticals, Inc. (Nasdaq: AVIR) (“Atea”), a clinical-stage biopharmaceutical company engaged in the discovery and development of oral antiviral therapeutics for serious viral diseases, today announced the outcome of the global Phase 3 SUNRISE-3 trial evaluating bemnifosbuvir, an oral nucleotide polymerase inhibitor, versus placebo for the treatment of COVID-19. The trial did not meet the primary endpoint of a statistically significant reduction in all-cause hospitalization or death through Day 29 in the monotherapy cohort of 2,221 high-risk patients with mild to moderate COVID-19. In SUNRISE-3, bemnifosbuvir was generally safe and well tolerated.

“We are disappointed by the outcome of the SUNRISE-3 trial. Variants of COVID-19 are constantly evolving and the natural history of the disease trended toward milder disease, which has resulted in fewer hospitalizations and deaths. In particular, hospitalization due to severe respiratory disease caused by COVID was not observed in SUNRISE-3, in contrast to our prior study. In an environment where there is much less COVID-19 pneumonia, it becomes more difficult for a direct-acting antiviral to demonstrate impact on the course of the disease,” said Jean-Pierre Sommadossi, PhD, Chief Executive Officer and Founder of Atea Pharmaceuticals. “I am proud of our team’s rigorous execution of this trial in a constantly changing pandemic environment.”

“We want to thank the study participants and investigators who made this important research possible. While we are disappointed with the outcome of trial and will not pursue a regulatory pathway forward, we believe that the findings add to the collective understanding of the evolution of COVID-19,” added Janet Hammond, MD, PhD, Chief Development Officer of Atea Pharmaceuticals.

Atea remains focused on the development of the combination of bemnifosbuvir and ruzasvir for the treatment of hepatitis C. The company plans to announce additional results from the Phase 2 trial in the fourth quarter of 2024.

About the Phase 3 SUNRISE-3 Trial in High-Risk Outpatients with COVID-19

The global, multicenter, randomized, double-blind, placebo-controlled Phase 3 SUNRISE-3 trial evaluated bemnifosbuvir or placebo administered concurrently with the locally available standard of care (SOC). SUNRISE-3 exclusively enrolled high-risk outpatients with mild or moderate COVID-19. Patients were randomized 1:1 to receive bemnifosbuvir 550 mg twice daily (BID) or placebo BID for five days.

The primary endpoint of the SUNRISE-3 trial was all-cause hospitalization or death through Day 29 in the supportive care monotherapy cohort. In addition, secondary endpoints measured patient outcomes in the trial through Day 60 post-treatment.

About Bemnifosbuvir

Derived from our internal discovery program, bemnifosbuvir, is an investigational, novel, orally administered guanosine nucleotide analog polymerase inhibitor that combines a unique nucleotide scaffold with novel double prodrugs for the intended purpose of inhibiting the enzymes central to viral replication. We believe that utilizing this double prodrug moiety approach allows us to maximize formation of the active metabolite potentially resulting in an oral antiviral product candidate that is selective for and highly effective at preventing replication and transcription of single stranded RNA (“ssRNA”) viruses while avoiding toxicity to host cells.

Bemnifosbuvir is in Phase 2 development in combination with ruzasvir, an oral NS5A inhibitor, for the treatment of hepatitis c virus (HCV) infection. Bemnifosbuvir has a low risk of drug-drug interactions, and has a generally safe and well-tolerated profile, with a distinct mechanism of action and a high barrier to treatment resistance.

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. 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 the anticipated timing of results from Atea’s Phase 2 trial of the combination of bemnifosbuvir and ruzasvir in the treatment of hepatitis C. When used herein, words including “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, 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 June 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.

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