Atea Pharmaceuticals Completes Patient Enrollment in Global Phase 3 SUNRISE-3 Trial Evaluating Oral Antiviral Bemnifosbuvir for COVID-19 in High-Risk Patients

March 27, 2024

Enrollment Reached Over 2,200 High-Risk Patients in Bemnifosbuvir Monotherapy Cohort

Results from SUNRISE-3 Expected in 2H'24

BOSTON, March 27, 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 that the company has completed enrollment of the global Phase 3 SUNRISE-3 trial evaluating bemnifosbuvir, an oral nucleotide polymerase inhibitor, or placebo for the treatment of COVID-19. Over 2,200 patients were randomized into the supportive care monotherapy cohort and less than 80 patients were randomized into the combination cohort. The primary endpoint of the trial is all-cause hospitalization or death through Day 29 post-treatment in the bemnifosbuvir supportive care monotherapy cohort of high-risk patients. Secondary endpoints include other measurements of patient outcomes through Day 60 post-treatment.

"COVID-19 continues to be a threat, leaving the most vulnerable at risk for severe outcomes from infection. The rapid pace of enrollment recently experienced in the monotherapy cohort of SUNRISE-3 highlights the continuing unmet medical need for new oral COVID-19 treatment options for high-risk patients, such as the elderly, immunocompromised and those with underlying risk factors," said Jean-Pierre Sommadossi, PhD, Chief Executive Officer and Founder of Atea Pharmaceuticals. "Since full enrollment was achieved ahead of the two planned interim analyses for safety and futility by the Data Safety Monitoring Board (DSMB), the analyses are no longer relevant, and in agreement with the DSMB, we will proceed to the full analysis of the trial. We look forward to reporting SUNRISE-3 results in the second half of 2024 with the goal of moving a step closer to providing a new oral antiviral treatment for people at high risk for COVID-19 progression."

Bemnifosbuvir was granted Fast Track designation by the U.S. Food and Drug Administration for the treatment of COVID-19.

About the Phase 3 SUNRISE-3 Trial

The global, multicenter, randomized, double-blind, placebo-controlled Phase 3 SUNRISE-3 trial is evaluating bemnifosbuvir or placebo administered concurrently with locally available standard of care (SOC). SUNRISE-3 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 trial is comprised of two study populations based on the type of SOC received: 1) the "supportive care population" evaluating bemnifosbuvir as monotherapy (primary analysis), and 2) the "combination antiviral population" assessing combination therapy if the SOC includes other compatible antiviral drugs against COVID-19 (secondary analysis).

The primary endpoint of the SUNRISE-3 study is all-cause hospitalization or death through Day 29 in the supportive care monotherapy cohort in approximately 2,200 high-risk patients. In addition, secondary endpoints will measure patient outcomes in the trial through Day 60 post-treatment.

In March 2024, enrollment for SUNRISE-3 was completed prior to the two scheduled interim analyses by the DSMB to assess safety and futility. Given that the trial has fully enrolled, the DSMB and Atea mutually concluded that both interim analyses would not be performed as they were no longer relevant. The interim analyses were originally planned to be conducted after approximately 650 and 1,350 evaluable patients in the monotherapy cohort, respectively, completed Day 29 post-treatment. Factoring the time required for full data analyses of SUNRISE-3 once patients have completed Day 60 post-treatment, Atea expects to report results from the SUNRISE-3 trial in the second half of 2024.

The SUNRISE-3 patient population consists of those aged ≥70 years (regardless of other risk factors), individuals aged ≥55 years with one or more risk factors, those aged ≥50 years with two or more risk factors, and individuals aged ≥18 years with specific risk factors, including immunocompromised conditions, irrespective of COVID-19 vaccination status. Additionally, patients with reduced renal function were eligible for enrollment.

About Bemnifosbuvir for COVID-19

Bemnifosbuvir targets the SARS-CoV-2 RNA polymerase (nsp12), a highly conserved gene which is responsible for both replication and transcription of SARS-CoV-2. Bemnifosbuvir has a unique mechanism of action, with dual targets consisting of chain termination (RdRp) and nucleotidyltransferase (NiRAN) inhibition, which has the potential to create a high barrier to resistance. *In vitro* data confirmed that bemnifosbuvir is active with similar efficacy against all variants of concern and variants of interest that have been tested, including Omicron subvariants BA.4, BA.5, XBB, EG.5.1 and JN.1.

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 the Company'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. Currently, Atea is focused on the development of orally-available antiviral agents for serious viral infections, including severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), the virus that causes COVID-19, and hepatitis C virus (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 the Company’s plans relating to and time of the anticipated release of the SUNRISE-3 results. When used herein, words including “expects,” “may,” “will,” “anticipates,” “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 the Company’s current expectations and various assumptions. The Company believes there is a reasonable basis for its expectations and beliefs, but they are inherently uncertain. The Company 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 important factors discussed and updated from time to time under the caption “Risk Factors” in the reports the Company files with the SEC, including annual reports on Form10-K, quarterly reports on Form10-Q, current reports on Form 8-K and other filings each of 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 the Company 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 the Company’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
Stern Investor Relations
212-362-1200
will.oconnor@sternir.com