Atea Pharmaceuticals Announces First Patient Dosed in SUNRISE-3 Phase 3 Registrational Trial of Bemnifosbuvir, an Investigational Oral Antiviral for the Treatment of COVID-19

November 29, 2022

Global Study to Evaluate Bemnifosbuvir as Monotherapy and in Combination in Non-Hospitalized Patients at High Risk of Disease Progression, Regardless of Vaccination Status

Phase 3 Evaluation of Bemnifosbuvir Supported by Clinical Data from Late-Stage MORNINGSKY Trial and Prior Studies

Bemnifosbuvir's Unique Mechanism with Dual Targets Creates a Higher Barrier to Resistance and Retains Antiviral Activity Against COVID-19 Variants

BOSTON, Nov. 29, 2022 (GLOBE NEWSWIRE) -- Atea Pharmaceuticals, Inc. (Nasdaq: AVIR) ("Atea"), a clinical-stage biopharmaceutical company, today announced the enrollment of the first patient in the SUNRISE-3 Phase 3 trial, a global multicenter trial evaluating bemnifosbuvir (AT-527) for the treatment of COVID-19 in non-hospitalized patients at high risk for disease progression to hospitalization and death. The patient was enrolled and dosed at a U.S. clinical trial site. The study is designed to enroll at least 1,500 patients with mild or moderate COVID-19, and the primary endpoint is all-cause hospitalization or death through Day 29 in at least 1,300 patients in the monotherapy arm. Bemnifosbuvir is an investigational orally administered, direct-acting antiviral derived from Atea's purine nucleotide prodrug platform.

"Our COVID-19 strategy for bemnifosbuvir is to focus on the highest unmet medical need. Our goal is to deliver a safe, effective and convenient treatment option for people that remain vulnerable to hospitalization or death due to the limitations of current antiviral treatments and the ability of the virus to evade vaccines and monoclonal antibodies," said Jean-Pierre Sommadossi, PhD, Chief Executive Officer and Founder of Atea Pharmaceuticals. "New variants not susceptible to currently available preventive tools are driving COVID-19 infection waves, which should enable timely patient enrollment in SUNRISE-3."

"COVID-19 remains a significant cause of morbidity and mortality, particularly in the elderly and immunocompromised. New oral antivirals, with improved profiles, are urgently needed to help those for whom currently available treatments are either unsuitable or ineffective," said Robert Murphy, MD, Executive Director of the Havey Institute for Global Health and the John Philip Phair Professor of Infectious Diseases at Northwestern University Feinberg School of Medicine.

Bemnifosbuvir, a nucleotide polymerase inhibitor, targets the SARS-CoV-2 RNA polymerase (nsp12), a highly conserved gene that is unlikely to change as the virus mutates and new variants continue to emerge. This gene 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 confirm that bemnifosbuvir is active with similar efficacy against all variants of concern or interest that have been tested, including Omicron subvariants BA.4 and BA.5.

About the Phase 3 SUNRISE-3 Trial
SUNRISE-3 is a randomized, double-blind, placebo-controlled, global Phase 3 trial to evaluate bemnifosbuvir or placebo administered concurrently with locally available standard of care (SOC). The study is designed to enroll at least 1,500 high-risk, non-hospitalized patients with mild or moderate COVID-19, with a global footprint of approximately 300 clinical trial sites in the United States, Europe, Japan and rest of the world. Patients will be randomized 1:1 to receive either bemnifosbuvir 550 mg twice-daily (BID) plus locally available SOC or placebo BID plus locally available SOC for five days.

This trial will be comprised of two populations derived from the type of SOC received. First, a "supportive care population" (the patient does not qualify for an authorized oral antiviral treatment or is in a region where oral antivirals are not locally available) which will assess bemnifosbuvir given as monotherapy. Second, a "combination antiviral population" which will assess combination therapy being bemnifosbuvir plus SOC if the SOC includes treatment with other COVID-19 antivirals.

The primary endpoint of the study is all-cause hospitalization or death through Day 29 in the supportive care population of at least 1,300 patients evaluating bemnifosbuvir as monotherapy. Secondary endpoints in the supportive care and combination antiviral populations include: COVID-19 complications, medically attended visits, symptom rebound / relapse and viral load rebound. Hospitalization and death have been the endpoints highly preferred by regulatory agencies, including the U.S. Food and Drug Administration.

The patient population will consist of those at high risk for disease progression, including patients ≥ 80 years old, patients ≥ 65 years old with at least one major risk factor, and immunocompromised patients ≥ 18 years old, all regardless of COVID-19 vaccination status.

About Bemnifosbuvir for COVID-19
Bemnifosbuvir is an investigational orally administered, non-mutagenic, non-teratogenic, direct-acting antiviral derived from Atea's purine nucleos(t)ide prodrug platform.

Results from the late-stage MORNINGSKY trial evaluating bemnifosbuvir for the treatment of COVID-19, showed a 71% reduction in hospitalization (secondary endpoint) with bemnifosbuvir versus placebo (p=0.047, unadjusted, exploratory) (n=207). In a subgroup analysis, patients > 40 years old had an 82% reduction in hospitalization. To date, 650 subjects have been exposed to bemnifosbuvir including 241 COVID-19 patients exposed to 550 mg or higher doses BID for 5 days. Results demonstrate a favorable profile, including clinical benefits in patient subsets, safety and tolerability

generally, and low risk of drug-drug interactions.

Bemnifosbuvir's profile supports the potential for bemnifosbuvir to become a cornerstone monotherapy and combination oral therapy for the treatment of COVID-19.

About Atea Pharmaceuticals
Atea is a clinical stage biopharmaceutical company focused on discovering, developing and commercializing oral therapies to address the unmet medical needs of patients with severe diseases. 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 severe 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 difficult-to-treat, severe viral infections, including severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), the virus that causes COVID-19, hepatitis C virus (HCV), dengue virus and respiratory syncytial virus (RSV). For more information, please visit www.ateapharma.com.

Forward-Looking Statements
This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements contained in this press release that do not relate to matters of historical fact should be considered forward-looking statements, including without limitation statements regarding our expectations surrounding the potential of our product candidates, including bemnifosbuvir combination product candidates, and expectations regarding our pipeline, including trial design and development timelines. These statements are neither promises nor guarantees, but involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements, including, but not limited to, the uncertainty around and costs associated with the clinical development of bemnifosbuvir as a potential treatment for COVID-19 and HCV and the clinical development of AT-752 for the potential treatment or prevention of dengue. These and other important factors discussed under the caption "Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2021 and our other filings with the SEC 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 we may elect to update such forward-looking statements at some point in the future, we disclaim any obligation to do so, even if subsequent events cause our views to change.

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