Atea to Advance Global Phase 3 Registrational Study of Bemnifosbuvir in High-Risk Non-Hospitalized Patients with COVID-19

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Novel Phase 3 Trial Design to Evaluate Bemnifosbuvir as Monotherapy and Combination Antiviral Therapy for COVID-19

Trial to Focus on High-Risk Patients at Greatest Risk for Disease Progression

Trial Expected to Initiate in Fourth Quarter 2022

Conference Call at 8:30 a.m. ET Today

BOSTON, Sept. 13, 2022 (GLOBE NEWSWIRE) -- Atea Pharmaceuticals, Inc. (Nasdaq: AVIR) ("Atea"), a clinical-stage biopharmaceutical company, today announced additional details on its clinical development plans for bemnifosbuvir for the treatment of COVID-19. Following meetings with the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA) Emergency Task Force, Atea plans to initiate a global Phase 3 registrational clinical trial of bemnifosbuvir for the treatment of COVID-19 in the fourth quarter of 2022. The trial will evaluate bemnifosbuvir as both monotherapy and combination antiviral therapy in outpatients (non-hospitalized) with COVID-19 who are at the highest risk of disease progression, regardless of vaccination status.

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 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.

"This novel Phase 3 trial design puts us at the forefront of clinical research for new COVID-19 antiviral therapies. In addition to the potential for an approval of bemnifosbuvir as a COVID-19 monotherapy, this trial will move the treatment field forward for combination antiviral therapy, which could be especially meaningful for people at the highest risk of disease progression," said Jean-Pierre Sommadossi, PhD, Chief Executive Officer and Founder of Atea Pharmaceuticals. "There is a need for safe and convenient therapies against COVID-19 for patients who may not benefit from currently available therapies. Bemnifosbuvir's results to-date, including clinical benefits, favorable safety and tolerability, and low risk of drug-drug interactions, demonstrate its potential to be a cornerstone therapeutic for monotherapy and combination therapy for the treatment of COVID-19."

Bemnifosbuvir targets 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. The inhibition of RNA polymerase has been shown *in vitro* to effectively block production of SARS-CoV-2. In addition, *in vitro* data confirm that bemnifosbuvir is active with similar efficacy against all variants of concern or interest that have been tested, suggesting antiviral activity against future variants. Bemnifosbuvir's unique mechanism with dual targets is designed to create a high barrier to resistance.

Global Phase 3 Registrational Study Design

The randomized, double-blind, placebo-controlled, global Phase 3 study will 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. 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 include two populations derived from the type of SOC received. They include 1) "Supportive care population" (the patient does not qualify for an approved antiviral treatment or where antivirals are not locally available) which will assess bemnifosbuvir given as monotherapy (primary analysis) and 2) "Combination antiviral population" which will assess combination therapy if the SOC includes treatment with other compatible antiviral drugs against COVID-19 (secondary analysis).

The primary endpoint of the study is all-cause hospitalization or death through Day 29 in the supportive care population in at least 1,300 patients. Secondary endpoints in each patient population include: COVID-19 complications, medically attended visits, symptom rebound / relapse and viral load rebound.

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

The study is expected to have a global footprint with approximately 300 clinical trial sites in the U.S., Europe, Japan and rest of the world.

Conference Call and Webcast

Atea will host a conference call and live audio webcast today at 8:30 a.m. ET. To access the live conference call, please register here. A live audio webcast of the call and accompanying slide presentation will also be available in the Events & Presentations section of the Company's Investor Relations website. An archived webcast will be available on the Atea website approximately two hours after the event.

About Atea Pharmaceuticals

Atea Pharmaceuticals is a clinical stage biopharmaceutical company focused on discovering, developing and commercializing oral therapies to address the unmet medical needs of patients with severe viral 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. 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.

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