Atea Pharmaceuticals Announces U.S. FDA Fast Track Designation Granted to Bemnifosbuvir, an Investigational Oral Antiviral, for the Treatment of COVID-19

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BOSTON, April 25, 2023 (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 United States Food and Drug Administration (FDA) has granted Fast Track designation (FTD) to bemnifosbuvir for the treatment of COVID-19. Bemnifosbuvir is an oral, direct-acting antiviral drug candidate being evaluated in the global Phase 3 SUNRISE-3 registrational trial for the treatment of COVID-19 in outpatients at high risk for disease progression regardless of vaccination status. This includes patients over the age of 80, patients 65 years or older with at least one major risk factor, and anyone over the age of 18 who is immunocompromised.

"The decision to grant FTD by the FDA for bemnifosbuvir reflects the continuing unmet medical need that remains for COVID-19 patients. FTD has the potential to expedite the development of bemnifosbuvir and we look forward to ongoing discussions with the FDA," said Jean-Pierre Sommadossi, PhD, Chief Executive Officer and Founder of Atea Pharmaceuticals. "Due to the limitations of current antiviral treatments, including drug-drug interactions and potential risks for genotoxicity and reproductive toxicity, as well as the ability of the virus to evade vaccines and monoclonal antibodies, new treatment options are urgently needed. In SUNRISE-3, we are targeting the most vulnerable patient populations who are at the greatest risk for disease progression to severe COVID-19 or mortality, and for whom there are currently the fewest treatment options."

About Bemnifosbuvir Fast Track Designation

The FDA's Fast Track program is designed to facilitate the expedited development and review of new drugs or biologics that are intended to treat serious or life-threatening conditions and demonstrate the potential to address unmet medical needs. Among other things, as a result of the Fast Track designation, Atea may benefit from more frequent communications with the FDA to discuss the development plan of bemnifosbuvir for the treatment of COVID-19 and rolling review of any completed sections of any resulting New Drug Application (NDA).

About the Phase 3 SUNRISE-3 Trial

SUNRISE-3 is a randomized, double-blind, placebo-controlled, global Phase 3 trial designed to evaluate bemnifosbuvir or placebo administered concurrently with locally available standard of care (SOC). It is expected that the study will enroll at least 1,500 high-risk, outpatients with mild or moderate COVID-19, with a global footprint of approximately 300 clinical trial sites planned 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 is 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 SUNRISE-3 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 both the supportive care and combination antiviral populations include: COVID-19 complications, medically attended visits, symptom rebound / relapse and viral load rebound.

The patient population enrolling in SUNRISE-3 consists 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, 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 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 inhibition of RNA dependent RNA polymerase (RdRp) and nucleotidyltransferase (NiRAN), 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 and BA.5. Bemnifosbuvir is currently being evaluated in SUNRISE-3, a global multicenter Phase 3 registrational trial 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 serious viral infections. Leveraging the Company's deep understanding of antiviral drug development, nucleos(t)ide chemistry, biology, biochemistry and virology, Atea is developing 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 through using its internal discovery capabilities augmented by in-licensing. 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 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 bemnifosbuvir as treatment for COVID-19 and the potential of the FTD to expedite its development. 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 timelines and costs associated with the clinical development of bemnifosbuvir as a potential treatment for COVID-19. 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, 2022 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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