Atea Pharmaceuticals Announces First Patient Dosed in Global Phase 3 MORNINGSKY Trial of AT-527 for Treatment of COVID-19

April 29, 2021

Phase 3 trial to evaluate efficacy and safety of AT-527, an oral antiviral for treatment of patients with mild to moderate COVID-19 in outpatient setting

BOSTON, April 29, 2021 (GLOBE NEWSWIRE) -- Atea Pharmaceuticals, Inc. (Nasdaq: AVIR) ("Atea"), a clinical-stage biopharmaceutical company, today announced that the first patient has been dosed in the Phase 3 MORNINGSKY trial, a global multicenter trial evaluating AT-527 in mild or moderate COVID-19 patients in an outpatient setting. The trial, which is anticipated to enroll approximately 1,400 non-hospitalized adults and adolescents with mild to moderate COVID-19, is currently enrolling patients at clinical trial sites outside the United States. MORNINGSKY is expected to have an extensive global footprint and will include a large number of clinical sites worldwide, including Japan.

AT-527 is an orally administered, direct-acting antiviral in development and derived from Atea's purine nucleotide prodrug platform. Under a strategic collaboration, Roche and Atea are jointly developing AT-527 for the treatment of COVID-19.

"This pivotal milestone demonstrates a focused effort with our strategic partner Roche to globally advance the development of an oral therapeutic for COVID-19 that has the potential for broad use in early stages of the disease," said Jean-Pierre Sommadossi, Ph.D., Founder and Chief Executive Officer of Atea Pharmaceuticals. "With the initiation of this global Phase 3 program, we are one step closer to achieving our goal of providing an easily administered oral, direct-acting antiviral in the fight against this global pandemic."

Dr. Sommadossi continued, "As a direct-acting antiviral, AT-527 aims to prevent disease progression by inhibiting viral replication and thereby reducing the severity of disease, preventing or shortening hospitalization, and also potentially preventing transmission of the virus to others. This makes it well-suited for potential use in both pre- and post-exposure prophylactic settings and complementary to vaccines."

AT-527 targets SARS-CoV-2 ribonucleic acid (RNA) polymerase (nsp12), a highly conserved gene which is responsible for both viral RNA replication and transcription. Given this preferential conserved target site, it is anticipated that the antiviral activity of AT-527 will continue even in the presence of naturally-evolving variants, which are now spreading globally.

About the Phase 3 MORNINGSKY Trial

MORNINGSKY is a Phase 3 multicenter, randomized, double-blind, placebo-controlled, outpatient study to evaluate the efficacy, safety, pharmacokinetic profile and antiviral activity of AT-527 in patients with mild or moderate COVID-19. The study is expected to enroll approximately 1,400 non-hospitalized patients, including adolescents with confirmed mild to moderate acute respiratory syndrome coronavirus-2 (SARS-CoV-2) infection. Patients will be randomized within 5 days of symptom onset. At the time of enrollment, patients must be stable and not require hospitalization. The primary endpoint, evaluating the efficacy of AT-527 compared with placebo, will measure the time to alleviation or improvement of COVID-19 symptoms. Other efficacy endpoints will include number of patients requiring medically attended visits or hospitalization for COVID-19. Additionally, among other secondary and exploratory endpoints, the study will also identify and/or evaluate biomarkers that are predictive of an antiviral response to AT-527.

About the AT-527 COVID-19 Clinical Development Program

AT-527 is an orally administered, direct-acting antiviral agent derived from Atea's nucleotide prodrug platform. AT-527 is currently under evaluation as a treatment for patients with COVID-19. In collaboration with Roche, in addition to the Phase 3 MORNINGSKY trial, AT-527 is currently being evaluated in a global Phase 2 study for hospitalized patients with moderate COVID-19 and a Phase 2 virology study in patients with mild or moderate COVID-19 in an outpatient setting.

About Atea Pharmaceuticals

Atea Pharmaceuticals is a clinical stage biopharmaceutical company focused on discovering, developing and commercializing therapies to address the unmet medical needs of patients with life-threatening 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 nucleotide 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. Currently, Atea is focused on the development of orally-available, potent, and selective nucleotide prodrugs for difficult-to-treat, life-threatening viral infections, including severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), the virus that causes COVID-19, dengue virus, hepatitis C virus (HCV) 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 safety, efficacy and demand for our product candidates, in particular AT-527; plans and timing for clinical trials and data; our strategic collaboration with Roche; our leadership; the sufficiency of our cash and cash equivalents to fund our operations; our competitive position and our participation in upcoming presentations and conferences. 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 following: uncertainty around and costs associated with the development of AT-527 as a potential treatment for COVID-19; dependence on management, directors and other key personnel; the impact of the COVID-19 pandemic on our business; our limited operating history and significant losses since inception; our need for substantial additional funding; our ability to use our net operating loss carryforwards; our dependence on the success of our most advanced product candidates; risks related to the regulatory approval process; risks associated with the clinical development process; risks related to healthcare laws and other legal compliance matters; risks related to potential commercialization; risks related to manufacturing and our dependence on third parties; risks relating to intellectual property; our ability to maintain effective internal control over financial reporting and the significant costs as a result of operating as a public company. 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, 2020 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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