Atea Pharmaceuticals Announces First Patient Dosed in Phase 2 Virology Trial of AT-527 in Outpatient Setting

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Trial to evaluate the virological efficacy of AT-527 on SARS-CoV-2 in patients with mild to moderate COVID-19

BOSTON, Feb. 04, 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 2 virology trial evaluating AT-527 in mild or moderate COVID-19 patients in an outpatient setting. The trial will enroll patients in the United Kingdom (UK), Ireland and other countries. AT-527 is an orally administered, direct-acting developmental antiviral agent derived from Atea's purine nucleotide prodrug platform.

"In collaboration with Roche, we are initiating a randomized virology study in the UK and Ireland, where COVID-19 is fast-spreading and an estimated 30-40% of new infections involve a new mutation. This study presents the opportunity to investigate the antiviral activity of AT-527 in these patients. Importantly, this study is evaluating patients in an outpatient setting, which is the anticipated patient population of the upcoming Phase 3 trial," said Jean-Pierre Sommadossi, Ph.D., Founder and Chief Executive Officer of Atea Pharmaceuticals. "While vaccines will play an important role in controlling the COVID-19 pandemic, we need additional treatment options to stay ahead of the virus, and direct-acting antivirals have the potential to be an essential complement to vaccines."

AT-527 has been shown to inhibit viral replication of SARS-CoV-2 in vitro. The ultimate goal is to effectively address the ongoing need for a safe and effective oral antiviral that is suitable for easy and early administration to reduce the severity of the disease, thereby reducing the burden on the global healthcare system.

The randomized, double-blind, placebo-controlled Phase 2 trial will evaluate the antiviral activity, safety, and pharmacokinetics of AT-527 550 mg twice-daily in adult patients with mild or moderate COVID-19 in an outpatient setting. There will be multiple cohorts included in the trial investigating potentially alternative dosing regimens in addition to the 550 mg twice-daily dosing. The study will enroll up to 220 patients in the UK, Ireland and other countries.

The primary endpoint of this trial is change from baseline in amount of SARS-CoV-2 virus RNA as measured by reverse transcription polymerase chain reaction (RT-PCR) at specified timepoints.

"We look forward to rapid enrollment of this important study and hope it will provide further evidence of AT-527's antiviral activity against SARS-CoV-2. Our goal is to provide as soon as possible an easily administered and widely accessible treatment to fight this global pandemic and to treat and curtail its spread worldwide," said Janet Hammond, MD, Ph.D., Chief Development Officer of Atea Pharmaceuticals.

About AT-527

AT-527 is an orally administered, direct-acting developmental antiviral agent derived from Atea's nucleotide prodrug platform. AT-527 is currently under evaluation as a treatment for patients with COVID-19. 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. A pivotal Phase 3 trial is planned in the 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, nucleoside biology, and medicinal chemistry, 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.

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