Atea Pharmaceuticals Presents Favorable Phase 1 Results for AT-527 at 28th Annual Conference on Retroviruses and Opportunistic Infections

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High Lung Levels of Active Triphosphate Predicted with Oral AT-527 for COVID-19 Patients

Data Supportive of AT-527 550 mg BID Dosing Regimen

BOSTON, March 06, 2021 (GLOBE NEWSWIRE) -- Atea Pharmaceuticals, Inc. (Nasdaq: AVIR) ("Atea"), a clinical-stage biopharmaceutical company, today presented results from the Phase 1 study of AT-527 in healthy volunteers at the 28th Annual Conference on Retroviruses and Opportunistic Infections (CROI) in a Science Spotlight presentation. AT-527 is an orally administered, direct-acting antiviral developmental agent derived from Atea's purine nucleotide prodrug platform and is in Phase 2 clinical development for the treatment of COVID-19. 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 emerging.

"We were delighted to present these encouraging results at CROI. Since the respiratory tract is the initiation site of the SARS-CoV-2 infection, these data demonstrate the potential for AT-527, our oral antiviral, to have meaningful clinical uptake in the lungs. Specifically, the data demonstrating rapid attainment of steady state with a fast build-up of trough levels enables us to predict that there should be exposure of drug in the lung above levels that are needed to inhibit viral replication," said Jean-Pierre Sommadossi, Ph.D., Chief Executive Officer and Founder of Atea Pharmaceuticals. "In addition, these results show that AT-527 was well tolerated with a favorable safety and pharmacokinetic profile and are supportive of the dosing regimen for the upcoming Phase 3 program."

In the Phase 1 study, 20 healthy volunteers were randomized 1:1 to receive oral AT-527 550 mg twice daily (BID) or matching placebo for 5 days. The purpose of this study was to assess the safety and pharmacokinetics (PK) of AT-527 in healthy volunteers and to predict human lung exposure of intracellular AT-9010, the active triphosphate (TP) metabolite of AT-527. Safety assessments included adverse events (AEs), vital signs, electrocardiograms (ECGs), and standard safety laboratory tests. Intensive PK sampling, performed after the first and last two doses, provided information on plasma exposures of AT-511, the free base of AT-527, a hemisulfate salt, and its metabolites including AT-273, the guanosine nucleoside metabolite, a measurable surrogate for intracellular AT-9010.

The study results showed AT-527 was well tolerated with a favorable safety profile. There were no discontinuations, serious AEs, clinically significant changes in vital signs, or ECGs observed. The data also demonstrated that AT-511 was rapidly absorbed, followed by fast and extensive stepwise metabolic activation ultimately to the intracellular TP metabolite AT-9010, reflected by plasma AT-273. AT-527 550 mg BID led to fast attainment of steady-state levels of AT-273 within two days of dosing. Plasma levels of AT-273 were further used to predict lung concentrations of AT-9010 using a scaling factor of 1.2X which was previously determined from *in vivo* tissue distribution of the triphosphate metabolite in cynomolgus monkeys. Beginning as early as three hours after the first dose, and maintained thereafter throughout the five days of dosing, predicted lung AT-9010 levels were consistently above the EC_{90} level of 0.5 µM for *in vitro* inhibition by the drug of SARS-CoV-2 replication. These results indicate the potential of AT-527 for the treatment of COVID-19 and are supportive of the dosing regimen of 550 mg BID.

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. In collaboration with Roche, 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. A pivotal Phase 3 trial is planned in the outpatient setting.

A direct-acting antiviral aims to prevent disease progression by minimizing or eliminating viral replication and thereby reducing the severity of the 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.

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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