Atea's AT-527, an Oral Antiviral Drug Candidate, Reduces Viral Replication in Hospitalized Patients with COVID-19 in Phase 2 Interim Analysis

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Phase 2 Interim Virology Results Indicate Rapid and Sustained Antiviral Activity Against SARS-CoV-2 in Patients with COVID-19 in the Hospitalized Setting

AT-527 is Being Studied in Multiple Clinical Studies, Including Global Phase 2 MOONSONG and Phase 3 MORNINGSKY Trials, with Results Expected During 2H 2021

BOSTON, Mass., June 30, 2021 (GLOBE NEWSWIRE) -- Atea Pharmaceuticals, Inc., a clinical-stage biopharmaceutical company engaged in the discovery and development of oral therapeutics for severe viral infections, today announced positive interim results from the global Phase 2 study evaluating AT-527 in hospitalized patients with mild-to-moderate COVID-19. Roche and Atea are jointly developing AT-527, an oral direct-acting antiviral (DAA) agent derived from Atea's purine nucleotide prodrug platform.

The interim analysis of the Phase 2 study included data from 70 hospitalized, high-risk patients with COVID-19 of which data from 62 patients were evaluable for virology analysis. Interim virology results indicated that AT-527 rapidly reduced viral load levels. At Day 2, patients receiving AT-527 experienced a 0.7 $\log_{10}$ (80%) greater mean reduction from baseline viral load as compared to placebo. A sustained difference in viral load reduction was maintained through Day 8.

AT-527's SARS-CoV-2 potent antiviral activity was also observed in patients with higher baseline viral loads above the median of 5.26 $\log_{10}$ as compared to placebo. When evaluating a strict RT-qPCR threshold of 500 copies/mL with no detectable ribonucleic acid (RNA) virus (target not detected, TND), the AT-527 arm achieved SARS-CoV-2 clearance as early as Day 2 (in 6% of patients), Day 8 (in 7% of patients) Day 10 (in 33% of patients), and Day 12 (in 31% of patients) compared to 0% of patients in the placebo arm at the same timepoints. By Day 14 (last viral sampling study day) approximately 47% of patients in the AT-527 arm and 22% in the placebo arm had no detectable RNA virus (TND). Nasopharyngeal swabs were measured in a reverse transcription polymerase chain reaction test (RT-qPCR) for the quantitative detection of nucleic acid from SARS-CoV-2.

Consistent with previous studies, AT-527 was generally safe and well tolerated. In this hospitalized study, there were no drug-related serious adverse events. Non-serious adverse events were equally distributed across treatment arms. Most were mild-to-moderate in severity and assessed as not related to the study drug. No safety concerns or newly determined risks were identified.

"We are very pleased with the potent antiviral activity of AT-527 demonstrated by the rapid inhibition of SARS-CoV-2 replication. Such potent activity may lead to faster recovery time for patients with COVID-19 while minimizing the transmission of infection," said Jean-Pierre Sommadossi, PhD, Chief Executive Officer and Founder of Atea Pharmaceuticals. "As COVID-19 continues to evolve worldwide, we need a multi-pronged approach to control this disease. AT-527, an oral, potent, target-specific DAA, may offer a convenient treatment to prevent disease progression and allow people to resume daily life more quickly, especially in areas where vaccines and antibody therapies are not readily available."

"The safety and tolerability profile for AT-527 continues to provide us with confidence that it has the potential to be used in hospitalized and outpatient settings for treatment and prophylaxis, which should significantly alleviate the burden on healthcare systems," said Janet Hammond, MD, PhD, Chief Development Officer of Atea. "As we continue to advance our clinical development program, we look forward to sharing further results and analyses, including reporting results from the Phase 2 MOONSONG virology study in the outpatient setting. This multi-cohort data from MOONSONG, which we expect in the third quarter, will further inform AT-527 dosing regimens in various clinical settings."

Final data from the full Phase 2 program will be submitted to an upcoming medical congress or a peer-reviewed publication.

About the Global Phase 2 Study of AT-527 in the Hospitalized Setting

The global Phase 2 trial in the hospital setting is a randomized, double-blind, placebo-controlled, multi-center study to evaluate AT-527 in patients with moderate COVID-19. Study objectives are to assess safety, tolerability, clinical and antiviral efficacy. Patients were randomized ≤ 5 days of symptom onset to receive either AT-527 550 mg twice-daily (BID) or placebo BID dosed for 5 days. The key inclusion criteria for this study were adult patients ≥ 18 years old with risk factors such as obesity, diabetes and hypertension.

Results from this Phase 2 study in hospitalized patients included pre-specified, interim virology data. This Phase 2 study was designed to gain confidence around the safety and tolerability of AT-527 and was not powered to show definitive clinical outcomes, which are being evaluated in the global Phase 3 MORNINGSKY trial.

The evaluation of infectious virus (viable virus able to replicate in cell culture) was an exploratory endpoint in this study and the current standard assay used was not able to measure the infectious virus in > 95% of the nasopharyngeal samples.

AT-527 Preclinical Update

Data from recently completed preclinical studies demonstrated that AT-527 inhibits SARS-CoV-2 through unique dual mechanisms targeting both RNA dependent RNA polymerase (RdRP) and the nidovirus RdRp-associated nucleotidyltransferase (NiRAN) of viral non-structural protein (nsp12) polymerase, which is essential for viral RNA replication and transcription. In addition, analysis of samples treated with AT-511 (the free base of AT-527)

by next generation sequencing (NGS) confirmed that AT-527 is not a mutagen and does not introduce mutations in the viral genome. These data will be submitted for peer-reviewed publication.

About the AT-527 COVID-19 Clinical Development Program

AT-527 is an oral 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, AT-527 is being evaluated in the global Phase 3 MORNINGSKY trial, a global Phase 2 study for hospitalized patients with moderate COVID-19 and a Phase 2 MOONSONG 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 oral 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 potential of our product candidates, in particular AT-527, and expectations regarding our pipeline. 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 and our other product candidates; 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 most recent Quarterly Report on Form 10-Q, 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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