Atea Pharmaceuticals Provides Update and Topline Results for Phase 2 MOONSONG Trial Evaluating AT-527 in the Outpatient Setting

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Topline Phase 2 MOONSONG trial results did not meet the primary endpoint in the overall population of patients with mild or moderate COVID-19, who were mostly low-risk with mild symptoms

In high-risk patients with underlying health conditions, a reduction of viral load of approximately 0.5 log_{10} at Day 7 was observed at 550 mg (prespecified subgroup analysis) and 1,100 mg BID (exploratory subgroup analysis) compared with placebo

Informed by results from MOONSONG, in addition to the positive interim Phase 2 trial results in hospitalized patients and other data, the Phase 3 MORNINGSKY trial protocol is being rapidly assessed for potential modifications

AT-527 was generally safe and well-tolerated in all studies to-date and has shown to be non-mutagenic with no effects on fertility and reproduction in non-clinical studies

Conference call at 8:30 a.m. ET today

BOSTON, Oct. 19, 2021 (GLOBE NEWSWIRE) -- Atea Pharmaceuticals, Inc. (Nasdaq: AVIR) ("Atea"), a clinical-stage biopharmaceutical company, today reported that the global Phase 2 MOONSONG trial evaluating AT-527 in the outpatient setting did not meet the primary endpoint of reduction from baseline in the amount of SARS-CoV-2 virus in patients with mild or moderate COVID-19 compared to placebo in the overall study population, of which approximately two thirds of patients were low-risk with mild symptoms. However, in high-risk patients with underlying health conditions, a reduction of viral load of approximately 0.5 log_{10} at Day 7 was observed at 550 mg (prespecified subgroup analysis) and 1,100 mg BID (exploratory subgroup analysis) compared with placebo.

Based on the MOONSONG topline and additional recent results for AT-527 as well as the evolving COVID-19 environment, Atea, together with Roche, are assessing potential modifications to the global Phase 3 MORNINGSKY trial including the trial's primary endpoint and patient population. As a result, we now anticipate Phase 3 MORNINGSKY data in the second half of 2022.

"The primary endpoint was not achieved in the overall study population in patients with mild or moderate COVID-19, however, MOONSONG topline data suggest that AT-527 has antiviral activity in high-risk patients with underlying health conditions as we previously reported in the Phase 2 hospitalized study. Based on these and other AT-527 data, we with our partner Roche, are assessing potential modifications to the Phase 3 MORNINGSKY protocol that may likely lead to improved clinical outcomes," said Jean-Pierre Sommadossi, PhD, Chief Executive Officer and Founder of Atea Pharmaceuticals. "We remain committed to our goal of developing and delivering AT-527 as an oral antiviral that will address treatment needs as COVID-19 continues to evolve."

Atea and Roche are jointly developing AT-527 as an oral direct-acting antiviral (DAA) for the treatment of COVID-19. Its unique mechanism of action, with dual targets including chain termination (RdRp) and NiRAN inhibition, has the potential to create a high barrier to resistance with broad antiviral coverage to different variants of SARS-CoV-2. Atea has completed a comprehensive nonclinical program to characterize the safety profile of AT-527. Results from these nonclinical studies demonstrate that AT-527 is non-mutagenic and has no effects on fertility and reproduction.

Topline Results of Global Phase 2 MOONSONG Trial of AT-527 in the Outpatient Setting

The global Phase 2 MOONSONG trial is a randomized, double-blind, multi-center, placebo-controlled trial, evaluating the antiviral activity, safety and pharmacokinetics of AT-527 550 mg (Cohort A, n=30) and 1,100 mg (Cohort B, n=30) administered twice daily (BID) in adult patients with mild or moderate COVID-19 versus placebo (n=40). The primary endpoint of this virology trial, which enrolled patients who were SARS-CoV-2 positive, is change from baseline in amount of SARS-CoV-2 virus RNA as measured by RT-PCR at specified timepoints.

In the topline analysis, treatment with AT-527 did not meet the primary endpoint as it did not show a clear reduction in SARS-CoV-2 viral load in the overall population of patients with mild or moderate COVID-19 compared to placebo. Overall, approximately two-thirds of the patients had mild symptoms with no underlying health conditions and were on average 37 years old. Additionally, COVID-19 vaccinated patients were among the patients included in the overall study population.

In high-risk patients with underlying health conditions, a reduction of viral load of approximately 0.5 log_{10} at Day 7 was observed with administration of 550 mg as compared to placebo (prespecified subgroup analysis Cohort A n=7; placebo n=11) and with administration of 1,100 mg BID as compared to placebo (exploratory subgroup analysis Cohort B; n=14; placebo n=7).

In addition to baseline patient characteristics, several factors may have impacted the MOONSONG data results, which evaluated viral kinetics. These potential factors include different variants emerging during the study, greater penetration of vaccinations within the enrolled population and a pooled placebo patient population. The pooled placebo patient population included different vaccination status (varying doses and vaccine types) and may have included different COVID-19 variants.

Consistent with previous studies, AT-527 was generally safe and well tolerated. In the MOONSONG study, the proportion of patients experiencing any adverse event (AE) was 20% in the placebo group, 20% in the AT-527 550 mg BID group (Cohort A) and 27% in the AT-527 1100 mg BID group

(Cohort B). There were 3 non-drug related serious adverse events (SAEs) in each of the treatment groups and all other AEs were grade 1 or 2. Gastrointestinal (GI)-related AEs were the most commonly reported AEs: 8% in the placebo group; 7% in the AT-527 550 mg BID group (Cohort A); 17% in the AT-527 1100 mg BID group (Cohort B), with mild to moderate nausea/vomiting resulting in premature study drug discontinuation of 3% in the placebo group, 0% in the AT-527 550 mg BID group (Cohort A) and 17% in the AT-527 1100 mg BID group (Cohort B). No clinically significant differences in laboratory abnormalities were observed in the treatment arms as compared to placebo.

"Based on the totality of the results for AT-527 to-date, the current level of understanding of the virus and the evolving COVID-19 environment, we are assessing the Phase 3 MORNINGSKY trial for modifications to ensure the best possible outcome for the program," said Janet Hammond, MD, PhD, Chief Development Officer of Atea Pharmaceuticals. "We, along with our partner Roche, are continuing to advance multiple studies in parallel to provide further clinical evidence as well as outcome data to support AT-527 as an oral, potent, direct-acting antiviral treatment for COVID-19."

In addition to the MOONSONG results announced today, results from the bronchoalveolar lavage study and Phase 2 hospitalized trial are being presented at the International Society for Influenza and Other Respiratory Virus Diseases (ISIRV)-World Health Organization Virtual Conference (WHO), in a poster and oral session held virtually October 19-21, 2021.

Conference Call and Webcast

Atea will host a conference call and live audio webcast to discuss these data today at 8:30 a.m. ET. To access the live conference call, please dial (833) 301-1150 (domestic) or (914) 987-7391 (international) at least five minutes prior to the start time and refer to conference 1186883.

A live audio webcast of the call and accompanying slide presentation will also be available in the Investors' Events & Presentations section of the Company's website, www.ateapharma.com. An archived webcast will be available on the Atea website approximately two hours after the event.

About the AT-527 COVID-19 Clinical Development Program

Derived from Atea's nucleos(t)ide prodrug platform, AT-527 is an oral direct-acting antiviral which is being studied to determine its potential to protect against disease progression, and the development of long-COVID complications. Its mechanism of action, with dual targets against a key viral enzyme, enhances its potential to limit resistance and work across variants. In collaboration with Roche, Atea is evaluating AT-527 across multiple Phase 2 and Phase 3 clinical trials that are advancing in parallel, including the global Phase 3 MORNINGSKY trial, a global Phase 2 study in hospitalized patients with moderate COVID-19, and the global Phase 2 MOONSONG virology study in patients with mild or moderate COVID-19 in an outpatient setting. In addition, MEADOWSPRING, a global Phase 3 long-term follow-on study, is evaluating the impact of AT-527 on long-term sequelae of COVID-19 in patients previously enrolled in MORNINGSKY.

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, AT-527, and expectations regarding our pipeline, including trial design and development timelines. 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 and reliance on interim or topline clinical trial results; 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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