Atea Announces Presentation of Bemnifosbuvir Data Demonstrating Reduced Hospitalizations for COVID-19 Patients at 2023 European Congress of Clinical Microbiology & Infectious Diseases

April 12, 2023

71% reduction in risk of hospitalization for mild to moderate COVID-19 outpatients treated with bemnifosbuvir versus placebo in MORNINGSKY study, regardless of vaccination status

BOSTON, April 12, 2023 (GLOBE NEWSWIRE) -- Atea Pharmaceuticals, Inc. (Nasdaq: AVIR) ("Atea"), a clinical-stage biopharmaceutical company engaged in the discovery and development of oral direct acting therapeutics for serious viral diseases, today announced the presentation of the full results from the MORNINGSKY Phase 3 trial evaluating bemnifosbuvir for the treatment of COVID-19. These results are being presented at the 33rd European Congress of Clinical Microbiology & Infectious Diseases (ECCMID), which is taking place April 15-18, 2023 in Copenhagen, Denmark. Bemnifosbuvir is an investigational, oral, direct-acting antiviral being developed for the treatment of COVID-19.

"With MORNINGSKY, in both low- and high-risk patients receiving bemnifosbuvir regardless of vaccination status, we see lower rates of hospitalization which is a clinically meaningful outcome," said Jean-Pierre Sommadossi, PhD, Chief Executive Officer and Founder of Atea Pharmaceuticals. "The MORNINGSKY data also highlight additional potential clinical benefits of bemnifosbuvir. We believe these data, together with bemnifosbuvir's favorable safety and drug-drug interaction profile, underscore its potential to address key unmet medical needs and limitations of current therapies for the treatment of COVID-19."

The MORNINGSKY results showed that non-hospitalized adult and adolescent patients receiving bemnifosbuvir for the treatment of mild to moderate COVID-19 experienced a 71% relative reduction in risk of hospitalization, regardless of vaccination status. In an exploratory analysis, an 82% reduction for hospitalization was seen in a subset of patients greater than 40 years of age. Topline results from the MORNINGSKY study were announced in May 2022.

Although the MORNINGSKY Phase 3 trial did not meet its primary endpoint of improved time for alleviation of COVID-19 symptoms, it was observed that patients treated with bemnifosbuvir experienced lower rates of hospitalization, medically attended visits, COVID-19-related complications and post treatment infections compared to patients receiving placebo. In this trial, bemnifosbuvir was generally safe and well tolerated, and there were no treatment related serious adverse events. Adverse events leading to treatment discontinuation were observed in 2.8% of patients treated with bemnifosbuvir compared to 7% of patients receiving placebo. Data from *in vitro* studies have demonstrated that bemnifosbuvir has no teratogenic or mutagenic effects and data from Phase 1 studies have shown low potential for bemnifosbuvir drug-drug interactions.

Based on these data, the global Phase 3 SUNRISE-3 registrational trial was initiated with an all-cause hospitalization or death primary endpoint in a high-risk population. Data presented at the 36th International Conference on Antiviral Research (ICAR) in March further support bemnifosbuvir's favorable safety and drug interaction profile.

Atea will also present clinical data for AT-752, an oral double prodrug of a guanosine nucleotide analog for the treatment of dengue virus, at ECCMID 2023. As part of a Phase 1 single and multiple ascending dose study, which evaluated the safety, tolerability and pharmacokinetics of AT-752, a concentration-QTc (C-QTc) analysis was conducted. Results indicated that AT-752 did not affect cardiac repolarization in healthy participants and that AT-752 was well tolerated after single and multiple oral doses.

Bemnifosbuvir for COVID-19

Poster Number: P2629
Date/Time: Monday, April 17, 2023,12:00 pm CET
Title: Bemnifosbuvir (AT-527) Treatment of Non-Hospitalized Individuals with Mild to Moderate COVID-19: Results from a Truncated Phase 3, Randomized, Double-Blind, Placebo-Controlled Trial (MORNINGSKY)

MORNINGSKY results showed that both vaccinated and unvaccinated patients with low and high risk for COVID-19 disease progression experienced a 71% relative reduction in risk of hospitalization with bemnifosbuvir (n=137) versus placebo (n=70). In an exploratory analysis of high-risk patients (greater than 40 years old; median age was 41 years old), there was an 82% relative risk reduction. Bemnifosbuvir was generally well tolerated.

MORNINGSKY was a randomized, double-blind, multi-center, placebo-controlled Phase 3 trial evaluating the efficacy, safety, antiviral activity, and pharmacokinetics of bemnifosbuvir in patients with mild to moderate COVID-19 randomized 2:1 to receive bemnifosbuvir 550 mg twice-daily or placebo in an outpatient setting. The primary endpoint of time to symptom alleviation was not met, however, a key secondary clinical efficacy endpoint showed a meaningful relative risk reduction in hospitalization and additional secondary clinical efficacy endpoints showed lower rates of COVID-19-related complications, medically attended visits, and post treatment infections compared with placebo. No clear differences in any of the virology endpoints between the bemnifosbuvir and placebo arms were observed. There were no deaths in the trial. As announced in December 2021, MORNINGSKY was closed out early, having enrolled 216 patients of which 207 patients were evaluable for efficacy. Bemnifosbuvir is currently being evaluated in the global Phase 3 SUNRISE-3 registrational trial (NCT05629962).

AT-752 for Dengue

Poster Number: P2941

Date/Time: Monday, April 17, 2023,12:00 pm CET
Title: AT-752, A Novel Nucleotide Prodrug With Pan-Serotype Activity Against Dengue Virus, Does Not Affect Cardiac Repolarization: Results From a Robust QT/QTc Evaluation in Healthy Participants

Results in healthy subjects (n=49) demonstrated that AT-752 was well tolerated and had no clinically relevant effects on cardiac repolarization, heart rate, PR (time between atrial depolarization and ventricular depolarization) or QRS (ventricular depolarization) intervals. The results showed that a QTc effect (in electrocardiography, the duration of the QT interval adjusted for the participant's heart rate) exceeding 10 milliseconds is unlikely across the full observed plasma concentration ranges of AT-281 (free base of AT-752) and metabolites.

While preclinical *in vitro* and *in vivo* data and the results from clinical trials indicate a favorable biological, pharmacological and safety profile for AT-752, Atea made the business decision in February 2023 to focus on its COVID-19 and hepatitis C virus (HCV) programs and to deprioritize its dengue program and the clinical development of AT-752.

About Bemnifosbuvir for COVID-19

Bemnifosbuvir, a nucleotide polymerase inhibitor, targets the SARS-CoV-2 RNA polymerase (nsp12), a highly conserved gene that is unlikely to change as the virus mutates and new variants continue to emerge. This gene is responsible for both replication and transcription of SARS-CoV-2. Bemnifosbuvir has a unique mechanism of action, with dual targets consisting of inhibition of RNA dependent RNA polymerase (RdRp) and nucleotityltransferase (NiRAN), which has the potential to create a high barrier to resistance. *In vitro* data confirm that bemnifosbuvir is active with similar efficacy against all variants of concern and variants of interest that have been tested, including Omicron subvariants BA.4 and BA.5. Bemnifosbuvir is currently being evaluated in SUNRISE-3, a global multicenter Phase 3 registrational trial for the treatment of COVID-19.

About Atea Pharmaceuticals

Atea is a clinical stage biopharmaceutical company focused on discovering, developing and commercializing oral therapies to address the unmet medical needs of patients with serious viral infections. Leveraging the Company's deep understanding of antiviral drug development, nucleos(t)ide chemistry, biology, biochemistry and virology, Atea has built a proprietary nucleos(t)ide prodrug platform to develop novel product candidates to treat single stranded ribonucleic acid, or ssRNA, viruses, which are a prevalent cause of serious viral diseases. Atea plans to continue to build its pipeline of antiviral product candidates by augmenting its nucleos(t)ide platform with other classes of antivirals that may be used in combination with its nucleos(t)ide product candidates. Currently, Atea is focused on the development of orally-available antiviral agents for serious viral infections, including severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), the virus that causes COVID-19, and hepatitis C virus (HCV). 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, including bemnifosbuvir for the treatment of COVID-19. 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. 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, 2022 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.

Contacts

Jonae Barnes
SVP, Investor Relations and Corporate Communications
617-818-2985
barnes.jonae@ateapharma.com

Will O'Connor
Stern Investor Relations
212-362-1200
will.oconnor@sternir.com