Atea Pharmaceuticals Highlights Strategic Priorities for 2023

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Enrollment Progresses in SUNRISE-3 Global Phase 3 Registrational Trial of Bemnifosbuvir in High-Risk Non-Hospitalized Patients with COVID-19 with Interim Analysis Expected 2H23

Proof-of-Concept Results for AT-752 for Dengue Expected 1Q23

Enrollment Expected to Initiate 2Q23 for Phase 2 Combination Trial of Bemnifosbuvir and Ruzasvir in Patients Infected with Hepatitis C Virus (HCV) with Initial Results Anticipated 4Q23

BOSTON, Jan. 09, 2023 (GLOBE NEWSWIRE) -- Atea Pharmaceuticals, Inc. (Nasdaq: AVIR) ("Atea"), a clinical-stage biopharmaceutical company, today provided an update on the company's clinical development programs for 2023, including its strategic priorities and expectations for achievement of a variety of milestones.

"Throughout 2022, our substantial clinical progress laid the foundation for a milestone-rich 2023. With an exciting year ahead, we expect to achieve a number of value-creating inflection points across all three of our clinical development programs for COVID-19, dengue and Hepatitis C," said Jean-Pierre Sommadossi, PhD, Chief Executive Officer and Founder of Atea Pharmaceuticals. "Importantly, we have a strong balance sheet from which to execute significant clinical milestones and to fund operations through 2025."

Bemnifosbuvir (AT-527) for COVID-19

SUNRISE-3 Global Phase 3 Registrational Study of Bemnifosbuvir in High-Risk Non-Hospitalized Patients with COVID-19: Patient enrollment continues in the randomized, double-blind, placebo-controlled, global Phase 3 SUNRISE-3 study evaluating bemnifosbuvir or placebo administered concurrently with locally available standard of care (SOC). The study is designed to enroll at least 1,500 high-risk, non-hospitalized patients with mild or moderate COVID-19, with an expected global footprint of approximately 300 clinical trial sites in the United States, Europe, Japan and rest of the world. Patients will be randomized 1:1 to receive either bemnifosbuvir 550 mg twice-daily (BID) plus locally available SOC or placebo BID plus locally available SOC for five days. An interim analysis is expected to be conducted in the second half of 2023.

This trial is comprised of two patient population cohorts derived from the type of SOC received. These are 1) "Supportive Care Population" (the patient does not qualify for an authorized oral antiviral treatment or is in a region where oral antivirals are not locally available) and bemnifosbuvir is evaluated as monotherapy (primary analysis for registration) and 2) "Combination Antiviral Population" which will assess combination therapy being bemnifosbuvir plus SOC if the SOC includes treatment with other COVID-19 antivirals (secondary analysis).

The primary endpoint of the study is all-cause hospitalization or death through Day 29 in the supportive care population in at least 1,300 patients. Secondary endpoints in each cohort include: COVID-19 complications, medically attended visits, symptom rebound / relapse and viral load rebound.

The patient population will consist of those at the highest risk for disease progression, including patients ≥ 80 years old, patients ≥ 65 years old with ≥ one major risk factor, and immunocompromised patients ≥ 18 years old, all regardless of COVID-19 vaccination status.

COVID-19 Program for Second Generation Protease Inhibitors: As part of a multipronged approach against COVID-19, Atea is advancing an internal program focused on the discovery of second-generation protease inhibitors that have clinical profiles appropriate for combination with bemnifosbuvir for the treatment of COVID-19. Atea's target profile for a protease inhibitor is a compound that is highly potent, has a favorable safety profile with limited drug-drug interactions and does not require a pharmacokinetic booster (e.g., ritonavir). The lead optimization of compounds is ongoing for the selection of a candidate that will next enter preclinical toxicology studies. Atea's goal for this program is to file an investigational new drug application / clinical trial application for a lead compound at the end of 2023.

The combination of bemnifosbuvir with the protease inhibitor nirmatrelvir was examined *in vitro* in an HCoV-229E surrogate model and results indicated an additive antiviral effect. These data support the potential benefit of the combination of bemnifosbuvir and a protease inhibitor for the treatment of SARS-CoV-2 infection.

AT-752 Program Update for Dengue

Global Phase 2 Dengue Study and Human Challenge Trial: Patient enrollment has been completed for the first cohort in the global Phase 2 DEFEND-2 (**DE**ngue **F**ever **END**) trial of AT-752 for the treatment of dengue. The randomized, double-blind, placebo-controlled study is designed to evaluate multiple doses of AT-752 in three distinct cohorts (~n=20 per cohort) and may enroll up to 60 adult patients infected with dengue. The primary objective of the study is to assess antiviral activity, with change from baseline dengue virus (DENV) viral load as the primary endpoint [DENV RNA by reverse transcription-polymerase chain reaction (RT-PCR)].

In addition, patient enrollment has been completed for the dengue human challenge model. This trial is designed to evaluate the effect of AT-752 in healthy volunteers who were challenged with an attenuated DENV-1 virus strain after receiving AT-752 or placebo.

Analysis of data from both studies is underway and proof-of-concept results are expected in the first quarter of 2023.

Hepatitis C Virus (HCV) Program Update

Phase 2 HCV Combination Program: Regulatory submissions for the Phase 2 combination study of bemnifosbuvir and ruzasvir (RZR) are ongoing. Atea expects to initiate patient dosing of the Phase 2 study during the second quarter of 2023 with initial data anticipated in the fourth quarter of 2023. This study will enroll approximately 280 HCV-infected, direct-acting antiviral naive patients across all genotypes, including a lead-in cohort of approximately 60 patients.

Patients will be administered 550 mg bemnifosbuvir in combination with180 mg ruzasvir once-daily for eight weeks.

The primary endpoints of the study are safety and sustained virologic response (SVR) at Week 12 post-treatment. Other virologic endpoints include virologic failure, SVR at Week 24 post-treatment and resistance.

Studies conducted by Atea have shown *in vitro* synergy from the combination of bemnifosbuvir and RZR in inhibiting HCV replication. In January 2022, Atea announced that it had obtained exclusive worldwide rights to develop, manufacture and commercialize RZR, an oral NS5A inhibitor, through a license agreement with Merck.

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 severe diseases. 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 severe 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 difficult-to-treat, severe viral infections, including severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), the virus that causes COVID-19, dengue virus 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 combination product candidates, 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 uncertainty around and costs associated with the clinical development of bemnifosbuvir as a potential treatment for COVID-19, the combination of bemnifosbuvir and ruzasvir for the potential treatment of HCV and AT-752 for the potential treatment of dengue. 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, 2021 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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