Atea Pharmaceuticals Announces Positive Initial Data from Phase 2 Study for Hepatitis C Virus (HCV) and Significant Enrollment Milestone for Phase 3 SUNRISE-3 Trial for COVID-19

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A 98% Sustained Virologic Response at Week 4 (SVR4) Post-Treatment Observed in Initial Data From 52 Patients in Lead-In Cohort in Phase 2 HCV Study

Phase 3 SUNRISE-3 Enrollment Surpassed 650 Patients in Monotherapy Arm; First Interim Analysis by the Independent Data Safety Monitoring Board (DSMB) Expected in March 2024

BOSTON, Jan. 08, 2024 (GLOBE NEWSWIRE) -- Atea Pharmaceuticals, Inc. (Nasdaq: AVIR) ("Atea"), a clinical-stage biopharmaceutical company engaged in the discovery and development of oral antiviral therapeutics for serious viral diseases, today announced the achievement of two significant clinical milestones from its Hepatitis C Virus (HCV) and COVID-19 programs. The Company reported positive initial data from the first 52 patients in the lead-in cohort of its Phase 2 combination 8-week study of bemnifosbuvir and ruzasvir (RZR) for the treatment of HCV. Additionally, Atea has enrolled more than 650 patients in the monotherapy arm of its Phase 3 SUNRISE-3 trial for the treatment of COVID-19, and enrollment continues with the current wave. This enrollment milestone allows for the first interim analysis of the study by the DSMB, which is expected this March.

Initial Phase 2 Data for HCV Combination Study

"We are excited to share that the initial data from the Phase 2 combination 8-week study showed a 98% SVR4, which exceeds our efficacy criterion of >90% for continuing the study. Based on these data, we plan to imminently reinitiate enrollment to complete the Phase 2 study and topline results are anticipated in the third quarter of 2024," said Jean-Pierre Sommadossi, PhD, Chief Executive Officer and Founder of Atea. "While direct acting antivirals have transformed HCV treatment, substantial unmet needs still exist, and the rate of new and reinfection currently exceeds cure rates in the US where 2.4 million individuals are estimated to be infected. The key unmet needs identified by healthcare providers in market research recently conducted by Atea include shorter length of treatment with fewer contraindications, particularly drug-drug interactions."

The Phase 2 open label study of bemnifosbuvir and RZR enrolled a lead-in cohort of 60 direct acting antiviral naïve, non-cirrhotic patients across all genotypes. Patients were administered 550 mg of bemnifosbuvir in combination with 180 mg of RZR once-daily for 8 weeks. Preliminary data are being presented as available, with SVR4 data currently available from 52 of the 60 lead-in patients. Including SVR4 as a decision endpoint, is a study design that is intended to substantially shorten the anticipated timeline for the completion of the Phase 2 trial. Clinical trials of other direct acting antiviral therapy combinations have demonstrated that the SVR4 result is highly correlated with SVR12.

The initial results for the first 52 patients who reached this timepoint demonstrated a SVR4 rate of 98%, including one patient with poor adherence who did not achieve SVR4. Additionally, very rapid kinetics were observed in all 60 patients across genotypes with viral load near or below the lower limit of quantification (LLOQ) at 4 weeks of treatment, which is supportive of an 8-week treatment regimen for the combination of bemnifosbuvir and RZR. All 60 patients achieved viral load below the LLOQ at the end of the treatment. The combination was generally safe and well tolerated. There were no drug related serious adverse events, no treatment discontinuations and adverse events were mostly mild.

The Phase 2 study aims to assess the safety and efficacy of 8 weeks of treatment with the combination of bemnifosbuvir and RZR in treatment-naïve HCV-infected patients, either without cirrhosis and or with compensated cirrhosis. The primary endpoint of the study is SVR12.

Approximately 280 treatment-naïve HCV-infected patients, including the lead-in cohort, are expected to be enrolled in the Phase 2 study. The second part of the trial is anticipated to enroll 220 patients across all genotypes. An expanded geographic footprint to include approximately 50 clinical sites in approximately 15 countries is currently being activated. Full enrollment of the study is expected to be completed by mid-2024 with topline results in the third quarter of 2024.

Phase 3 SUNRISE-3 Trial Enrollment Update

"Patient enrollment for SUNRISE-3 is currently correlating with the winter wave, and the high incidence of COVID-19 infection early in this winter season has led to more than 650 patients being enrolled. This is an important milestone, which allows for the first interim analysis by the independent DSMB for safety and futility, and the analysis is expected this March," continued Dr. Sommadossi. "COVID-19 remains a continuing threat to many worldwide, with the levels in wastewater higher than this time last year, and COVID-19 continues to be a leading driver of respiratory virus hospitalizations. There is a need for new treatment options to protect those who are most vulnerable to severe outcomes after infection such as the elderly, immunocompromised and those with underlying risk factors."

SUNRISE-3 is a global, multicenter, randomized, double-blind, placebo-controlled, registrational Phase 3 trial evaluating bemnifosbuvir or placebo administered concurrently with locally available standard of care (SOC). The study has a large global footprint targeting approximately 300 clinical trial sites in the U.S., Europe, Japan and rest of the world. Patients are randomized 1:1 to receive either bemnifosbuvir 550 mg twice-daily (BID) or placebo BID for five days. SUNRISE-3 is the only Phase 3 program in high-risk COVID-19 patients with hospitalization as a primary endpoint.

This trial is comprised of two study populations based on the type of SOC received: 1) bemnifosbuvir as monotherapy (primary analysis), and 2) the "combination antiviral population," assessing combination therapy if the SOC includes other compatible antiviral drugs against COVID-19 (secondary analysis).

The SUNRISE-3 patient population includes those aged ≥70 years (regardless of other risk factors), individuals aged ≥55 years with one or more risk factors, those aged ≥50 years with two or more risk factors, and individuals aged ≥18 years with specific risk factors, including immunocompromised conditions, all irrespective of COVID-19 vaccination status.

The primary endpoint of the trial is all-cause hospitalization or death through Day 29 post-treatment in the monotherapy arm in 2,200 patients. The trial includes two interim analyses by the DSMB to assess safety and futility, to be conducted after approximately 650 and 1,350 evaluable patients, respectively, after completion of Day 29 post treatment in the monotherapy arm.

About Bemnifosbuvir and Ruzasvir for HCV

Bemnifosbuvir, a nucleotide polymerase inhibitor, has been shown to be approximately 10-fold more active than sofosbuvir (SOF) *in vitro* against a panel of laboratory strains and clinical isolates of HCV genotypes 1–5. *In vitro* studies demonstrated bemnifosbuvir remained fully active against SOF resistance-associated strains (S282T), with up to 58-fold more potency than SOF. The pharmacokinetic (PK) profile of bemnifosbuvir supports once-daily dosing for the treatment of HCV and bemnifosbuvir has been well-tolerated at doses up to 550 mg for durations up to 8-12 weeks in healthy and HCV-infected subjects.

RZR, an oral NS5A inhibitor, has demonstrated highly potent and pan-genotypic antiviral activity in preclinical (picomolar range) and prior clinical studies. RZR has been administered to over 1,200 HCV-infected patients at daily doses of up to 180 mg for 12 weeks and has demonstrated a favorable safety profile. RZR's PK profile supports once-daily dosing.

About Bemnifosbuvir for COVID-19

Bemnifosbuvir targets the SARS-CoV-2 RNA polymerase (nsp12), a highly conserved gene which is responsible for both replication and transcription of SARS-CoV-2. Bemnifosbuvir has a unique mechanism of action, with dual targets consisting of chain termination (RdRp) and nucleotityltransferase (NiRAN) inhibition, which has the potential to create a high barrier to resistance. *In vitro* data confirmed 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, BA.5, XBB and EG.5.1.

About Atea Pharmaceuticals

Atea is a clinical stage biopharmaceutical company focused on discovering, developing and commercializing oral antiviral 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 in particular the combination of bemnifosbuvir and RZR for the potential treatment of HCV and bemnifosbuvir for the potential treatment of COVID-19, 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 possibility that final data from completed clinical trials may vary, potentially materially, from initial data reported from a subset of patients and other uncertainties associated with the clinical development of the combination of bemnifosbuvir and RZR as a potential treatment for HCV and bemnifosbuvir as a potential treatment for COVID-19. 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.

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