Atea Announces Presentation of Data Highlighting Favorable Safety Profile of Bemnifosbuvir at ESCMID Global 2024

April 29, 2024

BOSTON, April 29, 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 presentation of Phase 1 data highlighting the safety profile of bemnifosbuvir, an oral nucleotide polymerase inhibitor, at the European Society of Clinical Microbiology & Infectious Diseases Global 2024 (ESCMID, formerly ECCMID), which is taking place April 27-30, 2024 in Barcelona, Spain.

“The results presented at ESCMID further support the favorable safety profile for bemnifosbuvir by demonstrating the lack of cardiotoxicity in healthy participants,” said Jean-Pierre Sommadossi, PhD, Chief Executive Officer and Founder of Atea Pharmaceuticals. “Our goal is to address the substantial unmet need for the treatment of COVID-19 and hepatitis C virus (HCV), which continues due to the limitations of available treatments. During the second half of 2024, we look forward to reporting results for bemnifosbuvir from our Phase 3 SUNRISE-3 trial for COVID-19 and results for the combination of bemnifosbuvir and ruzasvir from our Phase 2 trial for HCV.”

Details for the poster presentation are as follows:

Poster Number: P0419
Abstract Number: 2927
Date and Time: April 27, 2024, 12:00 PM CET
Title: A Phase 1, Concentration-QTc Analysis Shows Bemnifosbuvir Does Not Alter Cardiac Repolarization

In this study, eligible healthy participants 18–65 years of age (n=42) were enrolled into multiple ascending dose cohorts and randomized to receive 550 mg, 825 mg or 1100 mg twice-daily oral bemnifosbuvir or matching placebo.

Results showed that the studied doses did not have any clinically relevant effect on cardiac repolarization, heart rate, PR interval (time between atrial depolarization and ventricular depolarization), or QRS (ventricular depolarization) duration. The results also demonstrated that a QTc effect (the duration of the QT interval adjusted for the participant’s heart rate) greater than 10 milliseconds (established threshold of regulatory concern) is unlikely across the full observed plasma concentration ranges of bemnifosbuvir and its metabolites.

These clinical data confirm the preclinical *in vitro* and *in vivo* study results, suggesting bemnifosbuvir has a low potential for cardiotoxicity with no predicted arrhythmic QTc-interval prolongation or inhibition of the human mitochondrial DNA-directed RNA polymerase.

About Bemnifosbuvir for COVID-19

The global Phase 3 SUNRISE-3 trial is evaluating bemnifosbuvir, an oral nucleotide polymerase inhibitor, or placebo for the treatment of COVID-19. SUNRISE-3 is a randomized, double-blind, placebo-controlled trial.

In March 2024, Atea completed enrollment of SUNRISE-3 with over 2,200 high-risk patients in the bemnifosbuvir monotherapy cohort. The primary endpoint of the trial is all-cause hospitalization or death through Day 29 post-treatment in the monotherapy cohort. In addition, secondary endpoints will measure patient outcomes in the trial through Day 60 post-treatment.

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 nucleotidyltransferase (NiRAN) inhibition, which have 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, EG.5.1 and JN.1.

About Bemnifosbuvir and Ruzasvir for Hepatitis C Virus (HCV)

Atea is currently conducting a global Phase 2 clinical trial of bemnifosbuvir in combination with ruzasvir, an oral NS5A inhibitor, in treatment-naïve, HCV-infected patients either without cirrhosis or with compensated cirrhosis. This study is designed to evaluate the safety and efficacy of eight weeks of treatment with the combination consisting of once-daily bemnifosbuvir 550 mg and ruzasvir 180 mg. Up to approximately 280 HCV-infected, treatment-naïve patients across all genotypes (GT), including the lead-in cohort of 60 patients without cirrhosis, are expected to be enrolled in this Phase 2 clinical trial.

The primary endpoints of the study are safety and sustained virologic response (SVR) at Week 12 post-treatment (SVR12). Other virologic endpoints include virologic failure, SVR at Week 24 post-treatment (SVR24) and resistance. Results from the 60 patient lead-in cohort demonstrated a 98% SVR4 rate across GT from 58 of 59 patients, which include a patient with poor adherence who did not achieve SVR4 and exclude one patient who did not attend the Week 4 post-treatment follow-up.

In *in vitro* studies, bemnifosbuvir has been shown to be approximately 10-fold more active than sofosbuvir (SOF) against a panel of laboratory strains and clinical isolates of HCV GT 1–5. *In vitro* studies have also 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. Across both HCV and COVID-19 programs, bemnifosbuvir has been administered to over 2,100 subjects and has been well-tolerated at doses up to 550 mg for durations up 12 weeks in healthy subjects and patients.

Ruzasvir has demonstrated highly potent and pan-genotypic antiviral activity in preclinical (picomolar range) and clinical studies. Ruzasvir 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. Ruzasvir's PK profile supports once-daily dosing.

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 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 includes "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements in this press release include but are not limited to the Company's plans relating to the time of the anticipated release of the COVID-19 SUNRISE-3 clinical trial results and the HCV Phase 2 clinical trial results. When used herein, words including "expects," "may," "will," "anticipates," "plans," and similar expressions are intended to identify forward-looking statements. In addition, any statements or information that refer to expectations, beliefs, plans, projections, objectives, performance or other characterizations of future events or circumstances, including any underlying assumptions, are forward-looking. All forward-looking statements are based upon the Company's current expectations and various assumptions. The Company believes there is a reasonable basis for its expectations and beliefs, but they are inherently uncertain. The Company may not realize its expectations, and its beliefs may not prove correct. Actual results could differ materially from those described or implied by such forward-looking statements as a result of various important factors, including, without limitation, the important factors discussed and updated from time to time under the caption "Risk Factors" in the reports the Company files with the SEC, including annual reports on Form10-K, quarterly reports on Form10-Q, current reports on Form 8-K and other filings each of which are accessible on the SEC's website at www.sec.gov. These and other important factors 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 the Company may elect to update such forward-looking statements at some point in the future, except as required by law, it disclaims any obligation to do so, even if subsequent events cause our views to change. These forward-looking statements should not be relied upon as representing the Company's views as of any date subsequent to the date of this press release.

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