Atea Pharmaceuticals Presents Favorable Drug Interaction Profile of Bemnifosbuvir in Phase 1 Studies at CROI 2023

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Results highlight the favorable profile for bemnifosbuvir related to low risk for drug-drug interactions

BOSTON, Feb. 23, 2023 (GLOBE NEWSWIRE) -- Atea Pharmaceuticals, Inc. (Nasdaq: AVIR) (“Atea”), a clinical-stage biopharmaceutical company, today announced that data from three Phase 1 studies suggest a favorable drug-drug interaction profile. No dosage adjustment is needed for CYP3A substrates or for drugs that are sensitive substrates of efflux and hepatic uptake transporters when co-administrated with bemnifosbuvir. CYP3A is an enzyme that metabolizes many classes of prescribed medicines and medicinal supplements, and efflux/hepatic uptake transporters regulate cellular trafficking of many drugs that are commonly prescribed to patients that are at high risk for severe COVID-19.

These results were presented at the Conference on Retroviruses and Opportunistic Infections (CROI), which took place February 19-22, 2023 in Seattle, Washington.

Bemnifosbuvir is an investigational orally administered, direct-acting antiviral. It is being evaluated in the global SUNRISE-3 Phase 3 registrational trial for the treatment of COVID-19 in non-hospitalized patients at high risk for disease progression to hospitalization and death.

“A key limitation of currently available treatments for COVID-19 is drug-drug interactions, especially for elderly and immunocompromised patients,” said Jean-Pierre Sommadossi, PhD, Chief Executive Officer and Founder of Atea Pharmaceuticals. “We are pleased that the clinical data presented at CROI demonstrate that bemnifosbuvir may be co-administered without drug-drug interactions with commonly prescribed therapeutics that patients may be taking for other conditions. In the Phase 3 SUNRISE-3 trial, we are targeting the most vulnerable patient populations who are at the greatest risk for disease progression to severe COVID-19 or mortality, and for whom there are currently the fewest treatment options.”

Poster Number: 512
Title: *No Dose Adjustments for CYP3A4 Substrates When Co-Administered with Bemnifosbuvir*

Results from a Phase 1, open-label, drug-drug interaction (DDI) study suggest that no dose adjustments are needed when bemnifosbuvir is co-administered with drugs that are substrates of CYP3A4.

In the study, bemnifosbuvir was administered with midazolam (MDZ; used as a sensitive CYP3A4 index drug) in 24 healthy participants and was well tolerated. Results showed a single dose (simultaneous or staggered) of bemnifosbuvir only slightly increased the plasma exposure of MDZ. After repeat dosing of bemnifosbuvir simultaneously administered with MDZ, bemnifosbuvir increased plasma MDZ (less than twofold) without affecting the exposure of the 1-hydroxymidazolam (1-OH-MDZ).

Poster Number: 513

Title: *Bemnifosbuvir Has Low Potential to Inhibit P-gp, BCRP and OATP1B1 Mediated Transport*

Results from two Phase 1, open-label, drug-drug interaction studies suggest bemnifosbuvir has low potential to exhibit clinically meaningful inhibition of P-glycoprotein (P-gp) or breast cancer resistance protein (BCRP)/organic anion transporter polypeptide 1B1 (OATP1B1) drug transporters. Therefore, no dose adjustment is expected for drugs that are sensitive substrates of these transporters when co-administered with bemnifosbuvir.

The efflux transporters P-gp and BCRP and the hepatic uptake transporter OATP1B1 regulate cellular trafficking of many drugs that are commonly prescribed to patients that are at high risk for severe COVID-19. These drugs include immunosuppressants, certain antibiotics, statins and other cardiovascular medications, certain diabetes medicines and chemotherapy.

The studies assessed the effect of bemnifosbuvir on digoxin (DIG) and rosuvastatin (ROSU), which were used as P-gp and BCRP/OATP1B1 index drugs, respectively.

Bemnifosbuvir administered with DIG or ROSU was well tolerated in the 29 healthy participants that were included in each study. A single high dose of bemnifosbuvir 1100 mg simultaneously administered with DIG slightly increased the C_{max} of DIG yet had no effect on its AUC, which is consistent with the transient nature of bemnifosbuvir plasma pharmacokinetics (PK). When dosed staggered, bemnifosbuvir did not affect the PK of DIG. A single dose (simultaneous or staggered) of bemnifosbuvir 1100 mg administered with ROSU slightly increased the plasma exposure of ROSU.

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 chain termination (RdRp) and nucleotityltransferase (NiRAN) inhibition, 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 or interest that have been tested, including Omicron subvariants BA.4 and BA.5. Bemnifosbuvir is currently being evaluated in SUNRISE-3, a global Phase 3 registrational study of bemnifosbuvir in high-risk non-hospitalized patients with 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, hepatitis C virus (HCV) and dengue virus. 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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