Atea Pharmaceuticals Highlights Strategic Priorities for 2022

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COVID-19: Planning global Phase 2 outpatient trial for bemnifosbuvir (AT-527) designed to support anticipated combination trials

HCV: Obtained from Merck an exclusive worldwide license to ruzasvir (RZR), a Phase 2-ready, oral, potent NS5A inhibitor for development in combination with bemnifosbuvir as a pan-genotypic regimen for hepatitis C (HCV)

Dengue: Initiating AT-752 Phase 2 proof-of-concept program for dengue fever

BOSTON, Jan. 07, 2022 (GLOBE NEWSWIRE) -- Atea Pharmaceuticals, Inc. (Nasdaq: AVIR) ("Atea"), a clinical-stage biopharmaceutical company, today provided an update on the company's clinical development priorities for 2022, including broadening its portfolio to include Phase 2 programs across three severe viral diseases. Atea is planning a global Phase 2 outpatient trial for bemnifosbuvir (AT-527) in COVID-19 that is designed to support anticipated combination trials. The Company is also initiating development of ruzasvir (RZR), a Phase 2-ready, next generation NS5A inhibitor in-licensed from Merck, in combination with bemnifosbuvir as a pan-genotypic regimen for the treatment of hepatitis C (HCV). In addition, Atea is advancing AT-752 to a Phase 2 proof-of-concept program for the treatment of dengue fever.

"We are executing on our strategy to build a leading antiviral company that is able to address severe viral diseases. The in-licensing of RZR supports the plan and enables the development of a potentially best-in-class pan-genotypic hepatitis C regimen in combination with bemnifosbuvir," Jean-Pierre Sommadossi, PhD, Chief Executive Officer and Founder of Atea Pharmaceuticals. "Nucleos(t)ide drugs are the backbone for oral combination treatment regimens which have had the greatest success in combatting severe RNA viral diseases and we foresee that bemnifosbuvir could also be a preferred backbone for protease inhibitors to treat COVID-19."

"We are expanding our pipeline in indications where we believe we can make a meaningful difference for patients with severe viral diseases. We expect to make important progress throughout the year and to advance Phase 2 programs in the three key indications of COVID-19, HCV and dengue fever," said Janet Hammond, MD, PhD, Chief Development Officer of Atea Pharmaceuticals. "Bemnifosbuvir's unique mechanism of action, combined with its efficacy and safety profile to-date, make it an ideal candidate for combination therapy with the potential to address unmet treatment needs for new waves of COVID-19 and HCV patients. In addition, we are advancing AT-752 into a Phase 2 proof-of-concept program for dengue fever. We look forward to reporting progress during the year with each of these programs."

Bemnifosbuvir COVID-19 Clinical Development Program Update

Building on the positive findings from Phase 2 clinical studies of bemnifosbuvir in high-risk patients with mild or moderate COVID-19, Atea plans to initiate a Phase 2 outpatient study designed to support anticipated clinical trials in combination with a protease inhibitor. This Phase 2 trial is designed to obtain additional safety, tolerability and virology data using a formulation with faster dissolution and absorption to enrich the data set from the previous Phase 2 studies. This trial is expected to enroll up to 200 high-risk outpatients with mild to moderate COVID-19. The Company expects to report topline data from this Phase 2 study in late 2022. The Phase 2 outpatient study replaces the Phase 2 study in hospitalized patients which Atea is currently closing out.

In addition to the clinical development of bemnifosbuvir, Atea is initiating preclinical *in vitro* combination studies of bemnifosbuvir with protease inhibitors to explore antiviral synergy and mitigation of potential viral resistance in connection with the use of protease inhibitors for the treatment of COVID-19.

About Ruzasvir (RZR) and Hepatitis C (HCV) Program with Bemnifosbuvir

Atea is announcing today that it has obtained exclusive worldwide rights to develop, manufacture and commercialize RZR, an oral NS5A inhibitor, through a recently completed license agreement with Merck. Under the terms of the agreement, Atea will pay Merck an upfront payment and Merck is eligible to receive additional payments associated with the achievement of certain development and commercial milestones as well as tiered royalties on product sales.

RZR has demonstrated highly potent antiviral activity in the picomolar range in preclinical studies. Clinical studies of RZR conducted by Merck showed a > 3 $\log_{10}$ viral load decline in HCV-infected patients as monotherapy. RZR has been administered to over 1,250 HCV-infected patients at daily doses of up to 180 mg for up to 24 weeks and has demonstrated a favorable safety profile with no consistent treatment-related changes in laboratory parameters. RZR's pharmacokinetic (PK) profile supports once-daily dosing.

Bemnifosbuvir 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. Bemnifosbuvir has been shown to be generally well tolerated in more than 480 subjects (including healthy volunteers and patients with HCV or COVID-19). Bemnifosbuvir's PK profile supports once-daily dosing for the treatment of HCV.

In vitro studies conducted by Atea have demonstrated synergy with bemnifosbuvir and RZR. Atea plans to initiate a Phase 2 combination study of bemnifosbuvir and RZR in the second half of 2022.

AT-752 Development Program for Dengue Fever Update

Atea successfully completed the Phase 1 clinical trial of AT-752. In the Phase 1 trial, AT-752 was well tolerated in 64 healthy subjects who were administered either single or multiple doses. No premature discontinuations due to adverse events or serious adverse events were reported and most adverse events were mild and there were no changes in laboratory parameters.

Atea plans to initiate a global Phase 2 proof-of-concept trial and a human challenge study in the US during the first half of 2022. Atea expects to report results from these studies in late 2022.

About Atea Pharmaceuticals

Atea Pharmaceuticals is a clinical stage biopharmaceutical company focused on discovering, developing and commercializing oral therapies to address the unmet medical needs of patients with life-threatening viral diseases. Leveraging the Company's deep understanding of antiviral drug development, nucleos(t)ide chemistry, biology, biochemistry and virology, Atea has built a proprietary nucleotide 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. Currently, Atea is focused on the development of orally-available, potent, and selective nucleotide prodrugs for difficult-to-treat, life-threatening viral infections, including severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), the virus that causes COVID-19, hepatitis C virus (HCV), dengue virus and respiratory syncytial virus (RSV). 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 Atea's expectations surrounding the potential of our product candidates, including bemnifosbuvir, AT-752 and RZR, and expectations regarding Atea's 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 Atea's actual results, performance or achievements to be materially different from any anticipated results, performance or achievements expressed or implied by the forward-looking statements, including, but not limited to, the following: uncertainty around and costs associated with the development of bemnifosbuvir as a potential treatment for COVID-19, the development of bemnifosbuvir and RZR as a potential treatment for HCV, and the development of AT-752 as a potential treatment for dengue fever; dependence on management, directors and other key personnel; the impact of the COVID-19 pandemic on our business; Atea's limited operating history and significant losses since inception; Atea's need for substantial additional funding; Atea's ability to use its net operating loss carryforwards; Atea's dependence on the success of its most advanced product candidates; risks related to the regulatory approval process; risks associated with the clinical development process and reliance on interim or topline clinical trial results; risks related to healthcare laws and other legal compliance matters; risks related to potential commercialization; risks related to manufacturing and our dependence on third parties; risks relating to intellectual property; Atea's ability to maintain effective internal control over financial reporting and the significant costs as a result of operating as a public company. These and other important factors discussed under the caption "Risk Factors" in Atea's most recent Quarterly Report on Form 10-Q and its 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 assumptions and expectations as of the date of this press release. While Atea may elect to update such forward-looking statements at some point in the future, it expressly disclaims any obligation to do so, even if subsequent events cause management's views to change.

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