Atea Pharmaceuticals Announces U.S. FDA Fast Track Designation Granted to AT-752 for Treatment of Dengue

September 26, 2022

Dengue is the most prevalent mosquito-borne viral disease; endemic to 100 countries worldwide, with more than half the world's populations at-risk

AT-752 is a novel, orally administered, direct-acting antiviral in Phase 2 development for treatment of dengue, showing potent in vitro and in vivo activity in preclinical studies and favorable safety and tolerability in a Phase 1 trial

BOSTON, Sept. 26, 2022 (GLOBE NEWSWIRE) -- Atea Pharmaceuticals, Inc. (Nasdaq: AVIR) ("Atea"), a clinical-stage biopharmaceutical company, today announced that the U.S. Food and Drug Administration (FDA) has granted Fast Track Designation to AT-752, a novel, orally administered, direct-acting antiviral for the treatment of dengue virus infection.

AT-752, a novel, orally administered direct-acting antiviral derived from Atea's purine nucleotide prodrug platform was designed for the treatment and prophylaxis of dengue. It works by impairing the dengue viral polymerase, which then inhibits replication of the virus. AT-752 is in Phase 2 clinical development and was generally well tolerated in a Phase 1 clinical study. In preclinical studies, AT-752 showed potent *in vitro* activity against all dengue serotypes, as well as potent *in vivo* antiviral activity in a small animal model.

"This Fast Track Designation underscores the urgent need for the development of effective treatments for this potentially severe viral disease as there are no currently approved treatments," said Jean-Pierre Sommadossi, PhD, Chief Executive Officer and Founder of Atea Pharmaceuticals. "This designation creates a potential opportunity to accelerate our efforts to develop AT-752 to address a critical unmet need for people worldwide."

"Dengue is the most prevalent mosquito-borne virus affecting up to 400 million people annually and is a substantial public health and economic burden worldwide. Dengue causes a severe generalized illness with fever which may require hospitalization and is associated with mortality. It is caused by an RNA virus which is transmitted by mosquitoes and may result in the potentially fatal clinical syndrome called dengue hemorrhagic fever," said Janet Hammond, MD, PhD, Chief Development Officer of Atea Pharmaceuticals. "We are advancing two proof-of-concept studies to demonstrate AT-752's safety and efficacy for the treatment and prophylaxis of dengue and look forward to initial data around the end of this year."

About AT-752 Fast Track Designation

The FDA's Fast Track program facilitates the expedited development and review of new drugs or biologics that are intended to treat serious or life-threatening conditions and demonstrate the potential to address unmet medical needs. Among other things, as a result of the Fast Track designation, Atea may benefit from more frequent communications with the FDA to discuss the development plan of AT-752 for the treatment of dengue virus infection and rolling review of any completed sections of a resulting New Drug Application (NDA).

About the AT-752 Clinical Program

Atea is currently conducting two clinical studies of AT-752. The first study is a global, randomized, double-blind, placebo-controlled Phase 2 trial in adult patients with dengue virus infection. The study is designed to evaluate the antiviral activity, safety and pharmacokinetics of multiple doses of AT-752 in areas where dengue is endemic. The second study is a human challenge study that is being conducted in the United States. The challenge study is designed to evaluate healthy subjects who are challenged with a Dengue Virus-1 Live Attenuated Virus strain after receiving AT-752 or placebo.

About Dengue

It is estimated that dengue accounts for up to 400 million infections a year globally, of which 100 million people get sick from the infection[1] and 500,000 cases[2] develop into life-threatening dengue hemorrhagic fever. Dengue infection is currently endemic in equatorial regions of the world, including Puerto Rico, Southeast Asia, Latin America and the Pacific Islands. Dengue occurs occasionally in the continental U.S. and other areas outside the endemic regions. However, because the types of mosquitoes that spread dengue are common in many parts of the continental U.S., local spread of the disease is possible. In addition, intercontinental jet transport, immigration, tourism, military operations and mosquito migration are increasing the direct effect of dengue on the global population.

Four serotypes of dengue viruses (DENV1–4) are common and a fifth serotype has been isolated but is yet to be fully characterized. As dengue serotypes are sufficiently different antigenically, infection with one serotype will confer lifelong immune protection against that serotype only, with only temporary, partial cross-immunity to other serotypes following recovery. A person can therefore potentially be infected with each of the four dengue serotypes in their lifetime. Subsequent infections with other serotypes increase the risk of developing severe disease due to antibody-dependent enhancement (ADE).

The World Health Organization has called dengue the most important mosquito-borne viral disease in the world. The FDA, together with other governmental and non-governmental agencies, recognize dengue as a substantial and growing global public health burden. Dengue is defined as a tropical disease under the U.S. Food, Drug and Cosmetic Act and, therefore, FDA approval of AT-752 for the treatment or prevention of dengue may result in the award of a tropical disease priority review voucher that may be used for a subsequent NDA or biologics license application.

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 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, 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 our expectations surrounding the potential of our product candidates, including AT-752, and expectations regarding the potential benefits of AT-752 for the treatment or prophylaxis of dengue virus infection, anticipated timing of initial clinical data from the ongoing clinical trials of AT-752 and the possibility that AT-752, if approved, may result in the award of a priority voucher. 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 AT-752 as a potential treatment or prophylaxis for dengue virus infection. 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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[1] https://www.cdc.gov/dengue/about/index.html

[2] https://apps.who.int/mediacentre/factsheets/fs117/en/index.html