

# Atea Pharmaceuticals Presents Favorable AT-752 Phase 1 Data for Treatment of Dengue Fever at American Society of Tropical Medicine & Hygiene 2022 Annual Meeting

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Safety and pharmacokinetic data in healthy volunteers support ongoing clinical development

AT-752 is a novel, orally administered, direct-acting antiviral in Phase 2 development with a Fast Track designation from the U.S. Food and Drug

Administration for treatment of dengue

Dengue is endemic in more than 100 countries putting greater than half the world's population at-risk for this mosquito-borne viral disease

BOSTON, Nov. 03, 2022 (GLOBE NEWSWIRE) -- Atea Pharmaceuticals, Inc. (Nasdaq: AVIR) ("Atea"), a clinical-stage biopharmaceutical company, today presented a poster highlighting favorable AT-752 Phase 1 clinical data for the treatment of dengue fever at the American Society of Tropical Medicine & Hygiene (ASTMH) 2022 Annual Meeting in Seattle, Washington.

The poster #1358, titled "Safety, tolerability, and pharmacokinetics of AT-752, a novel nucleotide prodrug with pan-serotype activity against dengue virus: results from a Phase 1, first-in-human, dose-escalation study," was presented by Xiao-Jian Zhou, PhD, Executive Vice President of Early Stage Development at Atea Pharmaceuticals.

"Dengue is the most prevalent mosquito-borne virus and despite its alarming increase over the last two decades, there are no direct-acting antiviral treatments available," said Jean-Pierre Sommadossi, PhD, Chief Executive Officer and Founder of Atea Pharmaceuticals. "These data demonstrate that AT-752 was well tolerated up to the highest dose tested and rapidly achieved plasma levels above the *in vitro* EC<sub>90</sub>. Based on these data, we anticipate that AT-752 may have the potential to rapidly inhibit dengue virus replication across all serotypes (1-5). In addition, AT-752 exhibited no pharmacokinetic sensitivity across varying ethnic populations participating in the trial."

"Importantly, these results support our advancement of two proof-of-concept studies to demonstrate AT-752's safety and efficacy for the treatment and potential prophylaxis of dengue," continued Dr. Sommadossi.

Atea is currently conducting two AT-752 clinical studies. 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 (PK) 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.

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. 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.

The U.S. Food and Drug Administration (FDA) has granted Fast Track Designation to AT-752 for the treatment of dengue virus infection.

### AT-752 Phase 1 Study Results

In the Phase 1 study, 65 healthy subjects aged 18–65 years old were sequentially enrolled into single ascending dose (SAD) and multiple ascending dose (MAD) cohorts and randomized to receive oral AT-752 or placebo. AT-752 was administered as a single oral dose up to 1500 mg, or as multiple oral doses up to 750 mg three times a day. In this study, AT-752 rapidly achieved plasma levels exceeding the *in vitro* EC<sub>90.</sub> AT-752 was generally safe and well tolerated and no premature discontinuations due to adverse events or serious adverse events were reported. Most adverse events were mild and there were no clinically relevant changes in laboratory parameters. AT-752 exhibited no PK sensitivity across varying ethnic populations participating in the trial and no food effect was seen.

The overall safety and PK results obtained in this Phase 1 study supported the initiation of two clinical studies of AT-752 for the treatment and prophylaxis of dengue infection.

## **About Dengue Fever**

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 and 500,000 cases 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 dengue serotype 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 <a href="https://www.ateapharma.com">www.ateapharma.com</a>.

# **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 and HCV and the clinical development AT-752 for the potential treatment and prevention 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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