



Atea Pharmaceuticals Introduces New Strategic Clinical Development Program for AT-527 in COVID-19

December 14, 2021

Responding to the rapidly evolving SARS-CoV-2, emerging variants and changing treatment landscape, Atea is updating the development strategy for AT-527

In addition to monotherapy evaluation, expanding development program to maximize AT-527's profile for potential use in combination therapy to meet the current and future needs of COVID-19 as it transitions to endemic

AT-527's differentiated mechanism of action with dual targets, including chain termination (RdRp) and NiRAN inhibition, may potentially provide a high barrier to resistance with broad antiviral coverage to coronaviruses and variants making its profile well suited for monotherapy and combination use

Initiating preclinical in vitro combination studies of AT-527 and other compounds with different mechanisms of action to evaluate additive and synergistic benefits

BOSTON, Dec. 14, 2021 (GLOBE NEWSWIRE) -- Atea Pharmaceuticals, Inc. (Nasdaq: AVIR) ("Atea"), a clinical-stage biopharmaceutical company, today announced an updated strategy for AT-527 to address the rapidly evolving SARS-CoV-2 and emerging variants by maximizing the compound's unique profile for potential use as both a monotherapy and in combination. Taking into account the changing COVID-19 landscape with the anticipated availability of new antiviral treatment regimens, the global Phase 3 MORNINGSKY trial will be closed out and the ongoing Phase 2 hospitalized trial will be further amended to expand enrollment to unvaccinated, high-risk outpatients. Atea expects to provide a more detailed update on its strategy and new development plan in 2022.

"We believe strongly in AT-527's potential to combat the evolving SARS-CoV-2 and emerging variants as a monotherapy and as an important backbone in potential combination therapy," said Jean-Pierre Sommadossi, PhD, Chief Executive Officer and Founder of Atea Pharmaceuticals. "Our new strategy enables us to rapidly drive forward a plan to maximize AT-527's unique profile with a development approach designed to meet the current and future needs of COVID-19, which may include the emergence of new variants and drug resistance to other therapies."

"The nucleoside class has been the cornerstone of effective oral antiviral combination treatments for severe viral diseases, and we are preparing for a future where combination regimens may be needed to treat COVID-19 as the virus and pandemic evolve. Importantly, we have the financial and internal resources to execute this strategy through key clinical and regulatory inflection points," added Dr. Sommadossi.

"After careful consideration of the rapid evolution of SARS-CoV-2 and the emergence of variants combined with the increasing availability of new COVID-19 treatment options, including the anticipated new antiviral regimens, continuing the MORNINGSKY trial is not the most effective path forward," said Janet Hammond, MD, PhD, Chief Development Officer of Atea Pharmaceuticals. "Our new development plan will leverage AT-527's unique profile with the objective to advance an oral, best-in-class, drug candidate that can be used broadly for the treatment of coronaviruses and for future pandemic preparedness."

Atea will continue to advance the global AT-527 Phase 2 trial evaluating the safety, tolerability and virological activity of AT-527 in unvaccinated patients with risk factors with moderate COVID-19. This ongoing study is currently exploring doses up to 1,100 mg BID in patients who are managed in a hospitalized or confined setting. Atea intends to further amend this study to remove the requirement for patient confinement or hospitalization. The amended Phase 2 trial is expected to enroll up to 200 patients. Atea anticipates reporting data from this trial during 2022. In addition, Atea is initiating preclinical *in vitro* combination studies of AT-527 and other compounds with different mechanisms of action to evaluate additive and synergistic benefits.

In addition to MORNINGSKY, the follow-on MEADOWSPRING trial will also be closed out. The strategic collaboration with Roche will be terminated on February 10, 2022.

About the AT-527 COVID-19 Clinical Development Program

Derived from Atea's nucleos(t)ide prodrug platform, AT-527 is an oral direct-acting antiviral which is being studied to determine its potential to protect against disease progression and the development of long-COVID complications. Its unique mechanism of action, with dual targets including chain termination (RdRp) and NiRAN inhibition, has the potential to create a high barrier to resistance with broad antiviral coverage to different variants of SARS-CoV-2. Atea has completed a comprehensive nonclinical program to characterize the safety profile of AT-527. Results observed from these nonclinical studies demonstrated that AT-527 was non-mutagenic, had no effects on fertility or reproduction and was non-teratogenic.

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, dengue virus, hepatitis C virus (HCV) 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-527 and AT-752, 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 following: uncertainty around and costs associated with the development of AT-527 as a potential treatment for COVID-19 and our other product candidates; dependence on management, directors and other key personnel; the impact of the COVID-19 pandemic on our business; our limited operating history and significant losses since inception; our need for substantial additional funding; our ability to use our net operating loss carryforwards; our dependence on the success of our 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; our 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 our most recent Quarterly Report on Form 10-Q, 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.

Contacts

Jonae Barnes
SVP, Investor Relations and Corporate Communications
617-818-2985
Barnes.jonae@ateapharma.com

Will O'Connor
Stern Investor Relations
212-362-1200
will.oconnor@sternir.com