Atea Pharmaceuticals Provides Clinical and Corporate Update and Reports Third Quarter 2021 Financial Results

November 11, 2021

Phase 3 MORNINGSKY Protocol Amendment to Include New Primary Endpoint, Refined Patient Population and Increased Dose, with Plan to Accelerate Completion of Enrollment

Infectious Virus Data Demonstrate AT-527's Rapid and Potent Antiviral Activity Against COVID-19 in Phase 2 MOONSONG Overall Patient Population Cohort B and High-Risk Patient Subgroup

New In Vitro Results Demonstrate AT-511 (Free Base of AT-527) Potent Activity Against COVID-19 Variants of Concern and/or of Interest, Including Delta

Conference Call at 4:30 p.m. ET Today

BOSTON, Nov. 11, 2021 (GLOBE NEWSWIRE) -- Atea Pharmaceuticals, Inc. (Nasdaq: AVIR) ("Atea"), a clinical-stage biopharmaceutical company, today reported financial results for the third quarter ended September 30, 2021 and provided a clinical and corporate update. Key highlights of today's announcement include a planned amendment to the global Phase 3 MORNINGSKY trial protocol, which will be submitted to health authorities, including in the U.S. The amendment includes a new primary endpoint, a refined patient population for enrollment and an increase in dosage. In addition, Atea announced that exploratory analyses of infectious virus from the Phase 2 MOONSONG trial indicate potent antiviral activity of AT-527 with a rapid reduction in viral load in the overall (low and high-risk) patient population and high-risk patient subgroup with AT-527 1,100 mg BID.

"New infectious virus data from a quantitative, highly-sensitive live virus assay further demonstrate AT-527's antiviral response potential. In the overall MOONSONG patient population, including low and high risk COVID-19 patients of whom the majority were seropositive, a rapid and potent viral load reduction was achieved with 1,100 mg twice-daily at Day 3 versus placebo. The antiviral effect was even more pronounced in the high-risk patient subgroup and a dose response was observed. These data support the findings from the Phase 2 trial conducted in hospitalized patients," said Jean-Pierre Sommadossi, PhD, Chief Executive Officer and Founder of Atea Pharmaceuticals.

"In addition to the notable infectious virus data from the MOONSONG study, new *in vitro* data indicate that AT-511 (free base of AT-527) is active against variants of concern and/or of interest, including Delta," continued Dr. Sommadossi. "These results, combined with the protocol amendment we are planning, increase our confidence in a favorable outcome for our Phase 3 MORNINGSKY study. We are working expeditiously to submit the MORNINGSKY protocol amendment and are committed to developing and delivering AT-527 as an oral antiviral that will address treatment needs for patients as COVID-19 continues to evolve."

Atea and Roche are jointly developing AT-527 as an oral direct-acting antiviral (DAA) for the treatment of COVID-19. 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.

Recent AT-527 Clinical Development Highlights

Quantitative Highly Sensitive SARS-CoV-2 Live Virus Assay Data: Additional data from the Phase 2 MOONSONG trial indicate the rapid and potent antiviral effect of AT-527 as measured by an infectious virus assay (detects the amount of "live" virus capable of replication). The analysis includes approximately 71% of all patients in MOONSONG (Cohort A and B) who had positive baseline cultures. These data support the findings observed in the Phase 2 trial in hospitalized patients with COVID-19 and indicate:

- A rapid and potent reduction in viral load of -0.5 $\log_{10}$ was observed in the evaluable patient population (low and high risk, majority seropositive) of Cohort B with 1,100 mg BID AT-527 (n=18) versus placebo (n=6) at Day 3 of the study period.
- A rapid and potent reduction in viral load of -0.9 $\log_{10}$ was observed in the high-risk patient subgroup (exploratory subgroup analysis) of Cohort B with 1,100 mg BID mg (n=11) versus placebo (n=4) at Day 3.
- A reduction in viral load of -0.3 $\log_{10}$ was observed in the high-risk patient subgroup (exploratory subgroup analysis) of Cohort A with 550 mg BID (n=8) versus placebo (n=6) at Day 3, suggesting a dose response for AT-527.

Global Phase 2 MOONSONG Trial of AT-527 in Outpatient Setting: In October, Atea reported that the global Phase 2 MOONSONG trial evaluating AT-527 in the outpatient setting did not meet the primary endpoint of reduction from baseline in the amount of SARS-CoV-2 virus evaluated by RT-PCR in patients with mild or moderate COVID-19 compared to placebo in the overall study population, of which approximately two thirds of patients were low-risk with mild symptoms. However, in high-risk patients with underlying health conditions, a reduction of viral load by RT-PCR of approximately -0.5 $\log_{10}$ at Day 7 was observed at 550 mg BID (prespecified subgroup analysis) and 1,100 mg BID (exploratory subgroup analysis) compared with placebo. For further information, you can access the press release in the Investors' News Release section of Atea's website.

Phase 3 MORNINGSKY Protocol Amendment and Plan to Accelerate Completion of Enrollment: Atea and Roche are submitting clinical trial

amendments for the global Phase 3 MORNINGSKY trial protocol to health authorities outside the US. Feedback on the amendment will also be obtained from the U.S Food and Drug Administration. The amendment includes the following:

- Changing the trial's primary endpoint to proportion of patients with COVID-19-related hospitalization or all-cause death. The previous primary endpoint of time to alleviation or improvement of COVID-19 symptoms will become a secondary endpoint.
- Refining the patient population to include only unvaccinated high-risk individuals
- Increasing the dose of AT-527 to 1,100 mg BID (twice-daily) from 550 mg BID

MORNINGSKY is a randomized, double-blind, multi-center, placebo-controlled Phase 3 trial evaluating the antiviral activity, safety and pharmacokinetics of AT-527 in approximately 1,600 patients (randomized 1:1 to receive AT-527 1,100 mg BID or placebo). To accelerate completion of enrollment, Atea and Roche plan to enhance the existing operational global infrastructure of the MORNINGSKY trial by leveraging existing clinical trial sites and expanding the footprint of MORNINGSKY to additional countries. The Phase 3 MORNINGSKY data are anticipated in the second half of 2022.

Patients enrolled in MORNINGSKY have the option to be enrolled in MEADOWSPRING, a six-month long-term follow-on study conducted in collaboration with Roche, to evaluate long COVID in patients who received AT-527 versus placebo in MORNINGSKY.

***In Vitro* Results Demonstrate AT-527 Is Active Against Different SARS-CoV-2 Variants Including Delta:** AT-511, the free base of AT-527, has been shown to be a potent inhibitor of SARS-CoV-2 *in vitro*. New results evaluating antiviral activity against variants of concern and/or of interest, including Alpha, Gamma, Epsilon and Delta, show that AT-511 maintains its potency against all the variants tested. These data confirm the key mechanistic advantage of the compound, which targets the highly conserved viral RNA polymerase.

Recent AT-752 Clinical Development Highlights

Phase 1 Trial of AT-752 for Dengue Fever: Following the successful completion of the single ascending dose escalation of AT-752 in the Phase 1 trial, the multiple ascending dose (MAD) portion of the trial was initiated and is currently ongoing. Atea plans to initiate a Phase 2 trial for AT-752 during the first half of 2022.

The Phase 1 trial is a randomized, double-blind, placebo-controlled study evaluating the safety, tolerability and pharmacokinetics of AT-752 in healthy volunteers. The study is expected to enroll up to 60 subjects.

In August 2021, Atea announced the publication of data demonstrating the *in vitro* and *in vivo* activity of AT-752 against dengue virus infection, in the journal "Antimicrobial Agents and Chemotherapy." The published data show AT-752 has potent *in vitro* activity against multiple dengue virus serotypes and other flaviviruses tested. AT-752 was also shown to reduce viremia and improve survival in an animal model of dengue disease.

Third Quarter 2021 Financial Results

***Cash and Cash Equivalents**:* $839.7 million at September 30, 2021 compared to $850.1 million at December 31, 2020.

Revenue: Collaboration revenue for the quarter ended September 30, 2021 in the amount of $32.8 million increased by $32.8 million from $0 million for the quarter ended September 30, 2020. All collaboration revenue was derived from the Roche License Agreement which was entered into in October 2020.

***Research and Development Expenses**:* Research and development expenses for the quarter ended September 30, 2021 in the amount of $43.0 million increased by $29.4 million from $13.6 million for the quarter ended September 30, 2020. The increase in research and development expenses was primarily due to increase in external expenses related to the CRO and CMO services in conjunction with the advancement of product candidates for the treatment of COVID-19 and dengue fever, including our share of costs incurred by Roche, and increases in internal spend primarily due to an increase in personnel-related expenses, including salaries, benefits and stock-based compensation expense for our research and product development employees and consulting fees and other research and development expenses.

***General and Administrative Expenses**:* General and administrative expenses for the quarter ended September 30, 2021 in the amount of $11.9 million increased by $7.9 million from $4.0 million for the quarter ended September 30, 2020. The increase in general and administrative expenses was primarily due to the expansion of our organization and reflected an increase in payroll and personnel-related expenses, including salaries, benefits and stock-based compensation expense and other general and administrative expenses.

Income Tax Expense: Income tax expense for the quarter ended September 30, 2021 in the amount of $6.1 million increased by $6.1 million from $0 million for the three months ended September 30, 2020. The increase in income tax expense was primarily due to realization of income as a result of the recognition of revenue in 2021 associated with the Roche License Agreement. The tax provision was calculated based on the year-to-date effective rate.

***Net Income (loss)**:* Net loss for the quarter ended September 30, 2021 in the amount of $28.2 million increased by $10.6 million from a net loss of $17.6 million for the quarter ended September 30, 2020.

Consolidated Statement of Operations and Comprehensive Income
(in thousands, except share and per share data)
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Collaboration revenue	$ 32,811	$ ---	$ 159,187	$ —
Operating expenses				
Research and development	43,019	13,601	109,394	24,177

General and administrative	11,939	4,028	32,597	7,500
Total operating expenses	54,958	17,629	141,991	31,677
Income (loss) from operations	(22,147)	(17,629)	17,196	(31,677)
Interest income and other, net	53	7	162	74
Income (loss) before income taxes	$ (22,094)	(17,622)	17,358	(31,603)
Income tax expense	(6,100)	—	(13,300)	—
Net Income (loss) and comprehensive income (loss)	$ (28,194)	$ (17,622)	$ 4,058	$ (31,603)
Net income (loss) per share attributable to common stockholders				
Basic	$ (0.34)	$ (1.74)	$ 0.05	$ (3.13)
Diluted	$ (0.34)	$ (1.74)	$ 0.05	$ (3.13)
Weighted-average shares outstanding				
Basic	82,815,636	10,109,847	82,727,268	10,099,134
Diluted	82,815,636	10,109,847	88,462,074	10,099,134

Selected Condensed Consolidated Balance Sheet Data
(Unaudited)

	September 30, 2021	December 31, 2020
Cash and cash equivalents	$ 839,660	$ 850,117
Total assets	843,504	863,632
Total liabilities	262,052	315,831
Total stockholders' equity	581,452	547,801

Conference Call and Webcast

Atea will host a conference call and live audio webcast to discuss the third quarter 2021 financial results and provide a corporate update today at 4:30 p.m. ET. To access the live conference call, please dial (833) 301-1150 (domestic) or (914) 987-7391 (international) at least five minutes prior to the start time and refer to conference ID 8846517.

A live audio webcast of the call and accompanying slide presentation will also be available in the Investors' Events & Presentations section of the Company's website, www.ateapharma.com. An archived webcast will be available on the Atea website approximately two hours after the event.

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 mechanism of action, with dual targets against a key viral enzyme, enhances its potential to limit resistance and work across variants. In collaboration with Roche, Atea is evaluating AT-527 across multiple clinical trials that are advancing in parallel, including the global Phase 3 MORNINGSKY trial. In addition, MEADOWSPRING, a global Phase 3 long-term follow-on study, is evaluating the impact of AT-527 on long COVID in patients who received AT-527 versus placebo in MORNINGSKY.

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.

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