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

August 12, 2021

- *New Data in Healthy Volunteers Confirmed that AT-527's Active Metabolite Achieved Target Antiviral Levels in Lungs, Key Site of COVID-19 Infection*
- *AT-527 Phase 2 Study Interim Results Showed Potent and Rapid Antiviral Activity in Hospitalized Patients; Study to Advance with Protocol Amendments Reflecting Evolving COVID-19 Environment*
- *Accruing Patients in Global Phase 3 MEADOWSPRING Follow-on Study to Evaluate AT-527 in Long COVID*
- *Global Phase 2 MOONSONG Results and Global Phase 3 MORNINGSKY Results Expected in 2H 2021*
- *Conference Call at 4:30 p.m. ET Today*

BOSTON, Mass., Aug. 12, 2021 (GLOBE NEWSWIRE) -- Atea Pharmaceuticals, Inc. (Nasdaq: AVIR) ("Atea"), a clinical-stage biopharmaceutical company, today reported financial results for the second quarter ended June 30, 2021 and provided a clinical and corporate update.

"We are very encouraged by new data, reported for the first time, that an investigational, direct-acting antiviral for COVID-19 achieved target drug levels in the lungs. In healthy volunteers, AT-527's active metabolite achieved target antiviral levels in lining fluid of the lungs, where SARS-CoV-2 virus replicates. These data not only provide further confidence for treatment but also support development of AT-527 for prophylaxis of COVID-19 and build upon our recent Phase 2 interim results showing treatment with AT-527 resulted in a rapid decline in viral load, which led to viral clearance. Impacting key sites of infection will be important in helping patients recover faster while minimizing virus transmission," said Jean-Pierre Sommadossi, PhD, Chief Executive Officer and Founder of Atea Pharmaceuticals.

"As COVID-19 becomes endemic and continues to evolve with the highly transmissible Delta variant and other variants, we need a multi-pronged treatment approach including safe and effective oral antiviral options that may play an important role in helping to reduce the global burden of disease," said Janet Hammond, MD, PhD, Chief Development Officer of Atea Pharmaceuticals. "We are very pleased with our results showing AT-527's strong antiviral potential and we continue to advance multiple global clinical studies in parallel with our collaborator Roche, to provide further clinical evidence in support of AT-527 as an oral, potent, direct-acting antiviral treatment for COVID-19."

Recent AT-527 Clinical Development Highlights

Drug Levels in Lung Lining Fluid in Healthy Volunteers: *First investigational direct-acting antiviral (DAA) being developed for COVID-19 to report target antiviral levels in lungs, primary site of infection for the virus*

- New results from a bronchoalveolar lavage (BAL) study in healthy volunteers showed AT-527's active metabolite achieved target antiviral levels in the lungs, where the SARS-Cov-2 virus replicates. The data show that target drug levels were achieved with AT-527 550 mg twice-daily (BID) dosing regimen leading to plasma and intrapulmonary (epithelial lining fluid, ELF) levels of AT-273 (surrogate of the active triphosphate metabolite) exceeding the target concentration.

New Preclinical and Clinical Results: *Expanding AT-527's favorable profile*

- Analysis of SARS-CoV-2 infected cells treated with AT-511 (the free base of AT-527) by next generation sequencing (NGS) confirmed that AT-527 is not a mutagen and does not introduce mutations in the viral genome.
- A new drug-drug interaction study in healthy volunteers indicated that no AT-527 dose adjustment should be necessary when co-administered with drugs that are CYP3A substrates as AT-527 is a weak inhibitor of CYP3A.

Global Phase 2 Trial of AT-527 in Hospitalized Setting: *Positive interim virology results demonstrated rapid and sustained viral load decrease and viral clearance*

- In June 2021, Atea announced a Phase 2 interim virology analysis of AT-527 550 mg BID dosing, which demonstrated a rapid reduction in viral load levels. The results included data from 70 hospitalized, high-risk patients with COVID-19 of which data from 62 patients were evaluable for virology analysis. At Day 2, patients receiving AT-527 experienced a 0.7 $\log_{10}$ (80%) greater mean reduction from baseline viral load versus placebo.

- AT-527's SARS-CoV-2 potent antiviral activity was also observed in patients with baseline viral loads above the median of 5.26 $\log_{10}$ as compared to placebo. The results showed that viral clearance of SARS-CoV-2 RNA in patients with higher baseline viral load (≥ median) was faster in patients treated with AT-527 versus placebo.

- Consistent with previous studies, AT-527 was generally safe and well tolerated. These interim results will be submitted for presentation at scientific meetings and to peer-reviewed publications. To access the press release reporting these results, click here.

Protocol Amendment for Global Phase 2 Study in Hospitalized Setting: *Reflecting evolving COVID-19 environment*

- The global Phase 2 study in the hospitalized setting is being amended with protocol changes emanating from the evolving COVID-19 environment which is reflected in the current standard of care and currently measurable study endpoints. The protocol amendments include changing the primary endpoint to virology, adding a Part B cohort comprised of up to 110 patients and exploring alternative doses.

Global Phase 2 MOONSONG Trial of AT-527 in Outpatient Setting: *Study ongoing with interim virology data expected in 2H 2021*

- Patient enrollment continues in the Phase 2 MOONSONG trial evaluating AT-527 in mild or moderate COVID-19 patients in an outpatient setting. The trial, which is being conducted in collaboration with Roche, may enroll up to 220 patients in multiple countries. The randomized, double-blind, multi-center, placebo-controlled trial is evaluating the antiviral activity, safety and pharmacokinetics of AT-527 550 mg, and other doses, administered BID in adult patients with mild or moderate COVID-19. The primary endpoint of this trial is change from baseline in amount of SARS-CoV-2 virus RNA as measured by reverse transcription polymerase chain reaction (RT-PCR) at specified timepoints.

Global Phase 3 MORNINGSKY Registrational Trial of AT-527 in Outpatient Setting: *Recruitment ongoing with results anticipated in 2H 2021*

- The global Phase 3 MORNINGSKY registrational clinical trial, being conducted in collaboration with Roche, is designed to enroll up to 1,400 patients globally. The randomized, double-blind, multi-center, placebo-controlled Phase 3 trial is evaluating the antiviral activity, safety and pharmacokinetics of AT-527 550 mg administered BID in adult patients with COVID-19 in an outpatient setting. The primary endpoint of this trial is time to alleviation or improvement of COVID-19 symptoms maintained for 24 hours.

Global Phase 3 Follow-on MEADOWSPRING Initiated: *Long-term study to understand the impact of AT-527 treatment on long COVID*

- MEADOWSPRING, a six-month long-term follow-on study conducted in collaboration with Roche, was recently initiated to evaluate the impact of prior administration of AT-527 on long COVID in patients previously enrolled in MORNINGSKY. This non-interventional study is expected to enroll approximately 1,000 patients and is currently accruing patients.

Recent AT-752 Clinical Development Highlights

Phase 1a Trial of AT-752 for Dengue Fever: *Completed single ascending dose portion and initiated multiple ascending dose portion*

- The Phase 1a single ascending dose study portion of the trial evaluating multiple doses has been successfully completed. The multiple-ascending dose portion of the trial was initiated during Q3 2021. The Phase 1a 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.

Recent Corporate Highlights

$50 Million Development Milestone Achieved Under License Agreement with Roche

- In June 2021, Atea announced the achievement of a milestone associated with the development of AT-527, and in July 2021, received a $50 million payment under its license agreement with Roche. Under the license agreement, Roche and Atea are jointly developing AT-527 for the treatment of COVID-19. Atea retains rights to commercialize AT-527 in the United States and Roche has the exclusive right to commercialize AT-527 outside of the United States.

Appointment of Jerome Adams, M.D., M.P.H., to Board of Directors

- In May 2021, Atea announced the appointment of Jerome Adams, M.D., M.P.H., to its Board of Directors. Dr. Adams most recently served as Surgeon General of the United States and brings a wide range of experience spanning clinical practice, clinical research, public health and government agency leadership.

Senior Management Appointment

- In June 2021, the Company announced the appointment of Claudio Avila, MB, BS, Ph.D., as Senior Vice President of

Medical Affairs. Dr. Avila previously served as Executive Director, U.S. Medical Strategy and Medical Affairs for COVID-19 at Gilead Sciences.

Second Quarter 2021 Financial Results

***Cash and Cash Equivalents**:* $816.5 million at June 30, 2021 compared to $850.1 million at December 31, 2020. The cash balance at June 30, 2021 does not include the $50 million milestone payment realized under the license agreement Atea entered into with F. Hoffmann-La Roche Ltd. and Genentech, Inc. in October 2020 ("Roche License Agreement"), which was received in July 2021.

Revenue: Collaboration revenue for the quarter ended June 30, 2021 in the amount of $60.4 million increased by $60.4 million from $0 million for the quarter ended June 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 June 30, 2021 in the amount of $39.8 million increased by $32.0 million from $7.8 million for the quarter ended June 30, 2020. The increase in research and development expenses was primarily due to an increase in external expenses incurred 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 June 30, 2021 in the amount of $11.9 million increased by $9.7 million from $2.2 million for the quarter ended June 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 June 30, 2021 in the amount of $7.2 million increased by $7.2 million from $0 million for the three months ended June 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 income for the quarter ended June 30, 2021 in the amount of $1.5 million increased by $11.5 million from a net loss of $10.0 million for the quarter ended June 30, 2020.

Selected Condensed Consolidated Balance Sheets
(in thousands, except share and per share amounts)
(Unaudited)

	June 30, 2021	December 31, 2020
Cash and cash equivalents	$ 816,460	$ 850,117
Accounts receivable	50,000	---
Total assets	871,543	863,632
Total liabilities	273,682	315,831
Total stockholders' equity	597,861	547,801

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Collaboration revenue	$ 60,391	$ ---	$ 126,376	$ —
Operating expenses				
Research and development	39,803	7,755	66,375	10,576
General and administrative	11,901	2,248	20,658	3,472
Total operating expenses	51,704	10,003	87,033	14,048
Income (loss) from operations	8,687	(10,003)	39,343	(14,048)
Interest income and other, net	52	10	109	67
Income (loss) before income taxes	8,739	$ (9,993)	$ 39,452	$ (13,981)
Income tax expense	(7,200)	---	(7,200)	---
Net Income (loss) and comprehensive income (loss)	$ 1,539	$ (9,993)	$ 32,252	$ (13,981)
Net income (loss) per share attributable to common stockholders				
Basic	$ 0.02	$ (0.99)	$ 0.39	$ (1.39)
Diluted	$ 0.02	$ (0.99)	$ 0.36	$ (1.39)

Weighted-average shares outstanding				
Basic	82,743,530	10,096,307	82,662,019	10,093,689
Diluted	88,091,384	10,096,307	88,683,767	10,093,689

Conference Call and Webcast

Atea will host a conference call and live audio webcast to discuss the second 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 5795073.

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

AT-527 is an oral direct-acting antiviral agent derived from Atea's nucleotide prodrug platform. AT-527 is currently under evaluation as a treatment for patients with COVID-19. In collaboration with Roche, AT-527 is being evaluated in the global Phase 3 MORNINGSKY trial, a global Phase 2 study for hospitalized patients with moderate COVID-19 and a Phase 2 MOONSONG virology study in patients with mild or moderate COVID-19 in an outpatient setting. In addition, MEADOWSPRING, a Phase 3 long-term follow-on study, will evaluate the impact of prior administration of AT-527 in long COVID.

A direct-acting antiviral aims to prevent disease progression by minimizing or eliminating viral replication and thereby reducing the severity of the disease, preventing or shortening hospitalization, and also potentially preventing transmission of the virus to others. This makes it well suited for potential use in both pre- and post-exposure prophylactic settings and complementary to vaccines.

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, AT-527, 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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