Atea Pharmaceuticals Reports Second Quarter 2023 Financial Results and Provides Business Update

August 8, 2023

- *Enrollment continues in global Phase 3 SUNRISE-3 trial evaluating bemnifosbuvir for treatment of COVID-19*
- *Phase 3 SUNRISE-3 trial protocol amended to broaden eligibility criteria for high-risk patients and adapt to current COVID-19 environment*
- *Enrollment continues in Phase 2 trial evaluating combination of bemnifosbuvir and ruzasvir for treatment of hepatitis C (HCV) with initial results expected in 4Q23*
- *Conference call at 4:30 pm ET today*

BOSTON, Aug. 08, 2023 (GLOBE NEWSWIRE) -- Atea Pharmaceuticals, Inc. (Nasdaq: AVIR) ("Atea"), a clinical-stage biopharmaceutical company engaged in the discovery and development of oral antiviral therapeutics for serious viral diseases, today reported financial results for the second quarter ended June 30, 2023 and provided a business update.

"We continue to advance the global Phase 3 SUNRISE-3 trial for COVID-19 with an expanded global footprint and protocol modifications designed to broaden the eligibility criteria for high-risk patients and increase the study sample size to reflect the current global hospitalization and death rates. Importantly, we do not anticipate that these modifications will change the timing for this trial, as we continue to expect topline results in mid-2024 and are currently targeting a New Drug Application submission by year-end 2024," said Jean-Pierre Sommadossi, PhD, Chief Executive Officer and Founder of Atea Pharmaceuticals. "Our strategy for COVID-19 is focused on delivering an effective treatment to the millions of patients for whom the current standard of care is not a suitable option."

"We have also advanced and are pleased with the progress of our Phase 2 combination study of bemnifosbuvir and ruzasvir for the treatment of HCV. During the second quarter of 2023, we began dosing HCV patients, and we look forward to reporting initial results from our lead-in cohort of approximately 60 patients by year-end 2023," continued Dr. Sommadossi. "Our goal for this program is to significantly improve upon the current standard of care by offering a short duration, pan-genotypic, protease inhibitor-free treatment for patients with HCV, with or without cirrhosis."

Bemnifosbuvir for COVID-19 Update

SUNRISE-3 Trial Protocol Amendment: Modifications of the SUNRISE-3 protocol are designed to broaden the high-risk patient population eligible for enrollment in the trial and to increase the study sample size to account for the lower rates of hospitalization and death that are being observed globally for COVID-19 in 2023 versus 2022.

With the amendment, the patient population will be expanded to include patients ≥70 years old (regardless of other risk factors), patients ≥55 years old with one or more risk factors, patients ≥50 years old with two or more risk factors and patients ≥18 years old with certain risk factors including immunocompromised conditions, all regardless of COVID-19 vaccination status. Also, patients with decreased renal function will be eligible for the trial.

Additionally, considering the currently observed low rates of hospitalization and death, the amendment modifies the trial from an adaptive design to a static design targeting enrollment of a fixed number of approximately 2,200 patients in the supportive care (monotherapy) arm compared with the original protocol which targeted approximately 1,300 patients in the same arm but allowed for a potential sample size re-estimation and increase following an interim analysis. The amendment also incorporates two interim analyses for review by the data and safety monitoring board principally for safety and futility after approximately 650 and 1,350 evaluable patients, respectively, in the supportive care (monotherapy) arm have completed Day 29.

Bemnifosbuvir SUNRISE-3 Trial in High-Risk Outpatients with COVID-19: Patient enrollment continues in the global, multicenter, randomized, double-blind, placebo-controlled, registrational Phase 3 SUNRISE-3 trial evaluating bemnifosbuvir, a nucleotide polymerase inhibitor, or placebo administered concurrently with locally available standard of care (SOC). SUNRISE-3 has a global footprint with a target of approximately 330 clinical sites in approximately 30 countries and is designed to enroll high-risk outpatients with mild or moderate COVID-19 at clinical trial sites worldwide, including in the U.S., Europe, and Japan. Patients are being randomized 1:1 to receive either bemnifosbuvir 550 mg twice-daily (BID) or placebo BID for five days.

The trial consists of two study populations derived from the type of SOC received: 1) "supportive care population" (those patients who do not qualify for an approved antiviral treatment or where antivirals are not locally available), which will assess bemnifosbuvir given as monotherapy (primary analysis) and 2) "combination antiviral population", which will assess combination therapy if the SOC includes treatment with other compatible antiviral drugs against COVID-19 (secondary analysis).

The primary endpoint of the SUNRISE-3 study is all-cause hospitalization or death through Day 29 in the supportive care (monotherapy) arm and is

powered to detect a clinically meaningful reduction in hospitalization or death versus placebo in this population.

Granted Fast Track Designation by U.S. FDA: In April 2023, Atea announced that the U.S. Food and Drug Administration (FDA) granted Fast Track designation to investigate bemnifosbuvir for the treatment of COVID-19. The FDA's Fast Track program is designed to facilitate 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 bemnifosbuvir for the treatment of COVID-19 and rolling review of any completed sections of any resulting New Drug Application.

Presentation of Data Showing Bemnifosbuvir Reduced Risk of Hospitalizations for COVID-19 Patients at 2023 European Congress of Clinical Microbiology & Infectious Diseases (ECCMID 2023): In April 2023, Atea presented the full results from the MORNINGSKY trial, which evaluated bemnifosbuvir for the treatment of mild to moderate COVID-19. As previously announced, these results showed that non-hospitalized adult and adolescent patients who received bemnifosbuvir experienced a 71% relative reduction in risk of hospitalization, regardless of vaccination status (secondary endpoint). In an exploratory analysis, an 82% reduction in risk of hospitalization was seen in a subset of patients greater than 40 years of age. Based on these data, the global Phase 3 SUNRISE-3 registrational trial was initiated.

COVID-19 Program for Second Generation Protease Inhibitors: As part of a multipronged approach against COVID-19, Atea is engaged in efforts directed to the discovery of second-generation protease inhibitors that have clinical profiles well suited for combination with bemnifosbuvir for the treatment of COVID-19. These efforts are supported by *in vitro* studies which have demonstrated that the combination of bemnifosbuvir and nirmatrelvir have an additive antiviral effect and the expectation that certain patient populations will require combination therapy. Activities to select a novel proprietary compound are underway.

Hepatitis C Virus (HCV) Program Update

Phase 2 HCV Combination Study: In June 2023, Atea initiated enrollment of a Phase 2 clinical trial of bemnifosbuvir in combination with ruzasvir in treatment-naïve, HCV-infected patients either without cirrhosis or with compensated cirrhosis. This study is designed to evaluate the safety and efficacy of eight weeks of treatment with the pan-genotypic combination consisting of once-daily bemnifosbuvir 550 mg and ruzasvir 180 mg. Approximately 280 HCV-infected, treatment-naïve patients across all genotypes, including a lead-in cohort of approximately 60 patients are expected to be enrolled in this Phase 2 clinical trial. The primary endpoints of the study are safety and sustained virologic response (SVR) at Week 12 post-treatment. Other virologic endpoints include virologic failure, SVR at Week 24 post-treatment and resistance. Initial data from the 60-patient lead-in cohort are anticipated in the fourth quarter of 2023.

The combination of bemnifosbuvir and ruzasvir has the potential to significantly improve upon the current standard of care by offering a differentiated short duration, pan-genotypic protease-inhibitor free regimen for HCV-infected patients with or without cirrhosis.

Second Quarter 2023 Financial Results

Cash, Cash Equivalents and Marketable Securities: $608.1 million at June 30, 2023 compared to $646.7 million at December 31, 2022.

Research and Development Expenses: Research and development expenses for the quarter ended June 30, 2023 in the amount of $22.1 million increased by $2.2 million from $19.9 million for the quarter ended June 30, 2022. The increase was primarily the result of higher expenses in connection with the SUNRISE-3 clinical trial for COVID-19 and Phase 2 clinical trial for HCV.

General and Administrative Expenses: General and administrative expenses remained relatively consistent at $13.2 million for the quarter ended June 30, 2023 compared to $12.4 million for the quarter ended June 30, 2022.

Interest Income and Other, Net: Interest income and other, net was $7.3 million for the quarter ended June 30, 2023 compared to $1.1 million for the quarter ended June 30, 2022. The increase was primarily the result of investing in higher yield marketable securities and higher interest rates.

Income Tax Expense: Income tax expense remained relatively consistent at $0.3 million for the quarter ended June 30, 2023 compared to $0.1 million for the quarter ended June 30, 2022.

Condensed Consolidated Statement of Operations and Comprehensive Income (Loss)
(in thousands, except share and per share amounts)
(unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Operating expenses				
Research and development	$ 22,063	$ 19,858	$ 51,017	$ 49,491
General and administrative	13,172	12,437	25,787	24,979
Total operating expenses	35,235	32,295	76,804	74,470
Income (loss) from operations	(35,235)	(32,295)	(76,804)	(74,470)
Interest income and other, net	7,303	1,080	13,602	1,178
Income (loss) before income taxes	(27,932)	(31,215)	(63,202)	(73,292)
Income tax expense	(251)	(120)	(448)	(120)
Net loss	$ (28,183)	$ (31,335)	$ (63,650)	$ (73,412)
Other comprehensive income:				
Unrealized (loss) gain on available-for- sale investments	(3)	---	374	---
Comprehensive loss	$ (28,186)	$ (31,335)	$ (63,276)	$ (73,412)

Net loss per share – basic and diluted	$ (0.34)	$ (0.38)	$ (0.76)	$ (0.88)
Weighted-average common shares used in computing net loss per share – basic and diluted	83,399,377	83,257,591	83,361,398	83,217,223

Selected Condensed Consolidated Balance Sheet Data
(in thousands)
(unaudited)

	June 30, 2023	December 31, 2022
Cash, cash equivalents and marketable securities	$ 608,062	$ 646,709
Working capital(1)	604,667	642,444
Total assets	626,028	666,708
Total liabilities	23,679	26,136
Total stockholders' equity	602,349	640,572

(1) The Company defines working capital as current assets less current liabilities. See the Company's condensed consolidated financial statements in its Quarterly Report on Form 10-Q for the three months ended June 30, 2023 for further detail regarding its current assets and liabilities.

Conference Call and Webcast

Atea will host a conference call and live audio webcast to discuss second quarter 2023 financial results and provide a business update today at 4:30 p.m. ET. To access the live conference call, please register here. 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. To participate via telephone, please register in advance here. Upon registration, all telephone participants will receive a confirmation email detailing how to join the conference call, including the dial-in number along with a unique passcode and registrant ID that can be used to access the call. While not required, it is recommended that participants join the call ten minutes prior to the scheduled start. An archived webcast will be available on the Atea website approximately two hours after the event.

About Bemnifosbuvir for COVID-19

Bemnifosbuvir, a nucleotide polymerase inhibitor, targets the SARS-CoV-2 RNA polymerase (nsp12), a highly conserved gene that is unlikely to change as the virus mutates and new variants continue to emerge. This gene is responsible for both replication and transcription of SARS-CoV-2. Bemnifosbuvir has a unique mechanism of action, with dual targets consisting of chain termination (RdRp) and nucleotidyltransferase (NiRAN) inhibition, which has the potential to create a high barrier to resistance. *In vitro* data confirmed that bemnifosbuvir is active with similar efficacy against all variants of concern and variants of interest that have been tested, including Omicron subvariants BA.4, BA.5 and XBB.

About Bemnifosbuvir and Ruzasvir for Hepatitis C Virus (HCV)

Bemnifosbuvir has been shown to be approximately 10-fold more active than sofosbuvir (SOF) *in vitro* against a panel of laboratory strains and clinical isolates of HCV genotypes 1–5. *In vitro* studies demonstrated bemnifosbuvir remained fully active against SOF resistance-associated strains (S282T), with up to 58-fold more potency than SOF. The pharmacokinetic (PK) profile of bemnifosbuvir supports once-daily dosing for the treatment of HCV and bemnifosbuvir has been well-tolerated at doses up to 550 mg for durations up to 8-12 weeks in healthy and HCV-infected subjects.

Ruzasvir (RZR), an oral NS5A inhibitor, has demonstrated highly potent and pangenotypic antiviral activity in preclinical (picomolar range) and clinical studies. RZR has been administered to over 1,200 HCV-infected patients at daily doses of up to 180 mg for up to 24 weeks and has demonstrated a favorable safety profile. RZR's PK profile supports once-daily dosing.

About Atea Pharmaceuticals

Atea is a clinical stage biopharmaceutical company focused on discovering, developing and commercializing oral antiviral therapies to address the unmet medical needs of patients with serious viral infections. 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 serious 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 serious viral infections, including severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), the virus that causes COVID-19, and hepatitis C virus (HCV). 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 bemnifosbuvir for the treatment of COVID-19, any new protease inhibitor we may advance for clinical development in combination with bemnifosbuvir for the treatment of COVID-19 and the combination of bemnifosbuvir and ruzasvir for the treatment of HCV. 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. 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, 2022 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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