Atea Pharmaceuticals Reports Third Quarter 2022 Financial Results and Provides Business Update

November 7, 2022

Enrollment of SUNRISE-3 Global Phase 3 Registrational Trial of Bemnifosbuvir in High-Risk Non-Hospitalized Patients with COVID-19 Expected Before Year-End 2022

Completion of Patient Enrollment Expected Around Year-End 2022 for AT-752 U.S. Human Challenge Study and for First Cohort of Global Phase 2 DEFEND-2 Trial for Dengue, Initial Data to Follow

Submission of Clinical Trial Applications for Combination Trial of Bemnifosbuvir and Ruzasvir for Hepatitis C (HCV) Anticipated Around Year-End 2022, Initiation of Phase 2 Trial Expected to Follow

Conference Call at 4:30 pm ET Today

BOSTON, Nov. 07, 2022 (GLOBE NEWSWIRE) -- Atea Pharmaceuticals, Inc. (Nasdaq: AVIR) ("Atea"), a clinical-stage biopharmaceutical company, today reported financial results for the third quarter ended September 30, 2022 and provided a business update.

"This year, we have made substantial progress advancing our three clinical candidates, which will make 2023 a pivotal year. We expect imminent enrollment of patients into SUNRISE-3 evaluating bemnifosbuvir for COVID-19. Around the end of the year, we anticipate completing enrollment in the AT-752 challenge study and the first cohort of DEFEND-2 with initial data to follow and submitting clinical trial applications for the bemnifosbuvir and ruzasvir combination hepatitis C study, leading to Phase 2 initiation," said Jean-Pierre Sommadossi, PhD, Chief Executive Officer and Founder of Atea Pharmaceuticals. "In addition, as part of our strategy for COVID-19, we continue to progress our second-generation protease inhibitor discovery program, focused on candidates with profiles that are well suited for combination therapy with bemnifosbuvir and expect to soon identify a candidate to advance toward the clinic."

"The rapid increase of multiple new variants in different regions coupled with the waning durability of immunity associated with vaccines and natural infections has led to predictions of further COVID-19 waves, which should enable an opportunity for patient enrollment in our SUNRISE-3 trial," continued Dr. Sommadossi. "In addition to relapse and safety concerns associated with current oral antivirals for COVID-19, the critical issue of drug-drug interactions with commonly prescribed life-saving drugs has led to a major unmet need among patients at high risk for severe disease including the elderly, those with COVID-19 risk factors and immunocompromised patients. Furthermore, monoclonal antibodies are largely ineffective against the newer COVID-19 variants leaving many without treatment options. There remains an urgent need for new COVID-19 oral therapeutics with a profile such as bemnifosbuvir, which has the potential to address the key limitations of current oral antivirals and is effective across all variants."

Bemnifosbuvir (AT-527) Program Update for COVID-19

SUNRISE-3: Global Phase 3 Registrational Study of Bemnifosbuvir in High-Risk Non-Hospitalized Patients with COVID-19: Before year-end 2022, Atea expects to begin enrollment of a randomized, double-blind, placebo-controlled, global Phase 3 study evaluating bemnifosbuvir or placebo administered concurrently with locally available standard of care (SOC). The study is designed to enroll at least 1,500 high-risk, non-hospitalized patients with mild or moderate COVID-19, with a global footprint of approximately 300 clinical trial sites in the United States, Europe, Japan and rest of the world. Patients will be randomized 1:1 to receive either bemnifosbuvir 550 mg twice-daily (BID) plus locally available SOC or placebo BID plus locally available SOC for five days.

This trial will be comprised of two populations derived from the type of SOC received. These are 1) "Supportive care population" (the patient does not qualify for an authorized oral antiviral treatment or is in a region where oral antivirals are not locally available) which will assess bemnifosbuvir given as monotherapy (primary analysis) and 2) "Combination antiviral population" which will assess combination therapy being bemnifosbuvir plus SOC if the SOC includes treatment with other compatible COVID-19 antivirals (secondary analysis).

The primary endpoint of the study is all-cause hospitalization or death through Day 29 in the supportive care population in at least 1,300 patients. Secondary endpoints in each patient population include: COVID-19 complications, medically attended visits, symptom rebound / relapse and viral load rebound.

The patient population will consist of those at the highest risk for disease progression, including patients ≥ 80 years old, patients ≥ 65 years old with ≥ one major risk factor, and immunocompromised patients ≥ 18 years old, all regardless of COVID-19 vaccination status.

Bemnifosbuvir Retains Antiviral Activity Against Omicron Subvariants BA.4 and BA.5 *In Vitro*: AT-511, the free base of bemnifosbuvir, has been shown to be a potent inhibitor of SARS-CoV-2 *in vitro*. New results demonstrated that AT-511 retained potent antiviral activity against the SARS-CoV-2 Omicron subvariants BA.4 and BA.5. AT-511 has previously demonstrated *in vitro* potent antiviral activity against other variants of concern and/or of interest, including Alpha, Beta, Gamma, Epsilon, Delta and Omicron subvariants BA.1 and BA.2.

Advancing Multipronged Approach for COVID-19 for Future Preparedness

COVID-19 Program for Second Generation Protease Inhibitors: As part of a multipronged approach against COVID-19, Atea is advancing an internal program focused on the discovery of second-generation protease inhibitors that have clinical profiles appropriate for combination with bemnifosbuvir for the treatment of COVID-19. Atea's target profile for a protease inhibitor is a compound that is highly potent, has a favorable safety profile with limited drug-drug interactions and does not require a booster (e.g., ritonavir). The lead optimization of compounds is ongoing for selection

of a candidate that will next enter preclinical toxicology studies.

The combination of bemnifosbuvir with the protease inhibitor nirmatrelvir was examined *in vitro* in an HCoV-229E surrogate model and results indicated an additive antiviral effect. These data support the potential benefit of the combination of bemnifosbuvir and a protease inhibitor for the treatment of SARS-CoV-2 infection.

AT-752 Program Update for Dengue

Global Phase 2 Dengue Study and Human Challenge Trial: Patient enrollment continues in the global Phase 2 DEFEND-2 (**DE**ngue **F**ever **END**) trial of AT-752 for the treatment of dengue. The randomized, double-blind, placebo-controlled trial is designed to evaluate multiple doses of AT-752 in three distinct cohorts (n=20 per cohort) and may enroll up to 60 adult patients infected with dengue. The primary objective of the trial is to assess antiviral activity, with change from baseline dengue virus (DENV) viral load as the primary endpoint [DENV RNA by reverse transcription-polymerase chain reaction (RT-PCR)].

In addition to the DEFEND-2 trial, Atea is enrolling a dengue human challenge trial. This trial, which is being conducted exclusively in the United States, is designed to evaluate the effect of AT-752 in healthy volunteers who are challenged with an attenuated DENV-1 virus strain after receiving AT-752 or placebo.

Patient enrollment in the human challenge trial and the first cohort of the DEFEND-2 study is expected to be completed around year-end 2022 with initial data to follow.

AT-752 Favorable Phase 1 Data Presented at American Society of Tropical Medicine & Hygiene 2022 Annual Meeting: Atea presented data from its Phase 1 study that demonstrated AT-752 rapidly achieved plasma levels exceeding the *in vitro* EC_{90} and was generally safe and well tolerated up to the highest does tested. No premature discontinuations due to adverse events or serious adverse events were reported, most adverse events in the study were mild and there were no clinically relevant changes in laboratory parameters. Additionally, the study results demonstrated that AT-752 may be taken with or without food and there was no pharmacokinetic sensitivity among varying ethnic populations. The results from this study and *in vitro* data demonstrating pan-serotypic activity supported the advancement of AT-752 into the DEFEND-2 trial and the human challenge study.

Hepatitis C Virus (HCV) Program Update

Phase 2 HCV Combination Program: Atea expects to submit clinical trial applications for the Phase 2 combination study of bemnifosbuvir and ruzasvir (RZR) around the end of the year with initiation of the Phase 2 trial to follow. Studies conducted by Atea have shown *in vitro* synergy from the combination of bemnifosbuvir and RZR in inhibiting HCV replication.

In January 2022, Atea announced that it had obtained exclusive worldwide rights to develop, manufacture and commercialize RZR, an oral NS5A inhibitor, through a license agreement with Merck.

Third Quarter 2022 Financial Results

Cash, Cash Equivalents and Marketable Securities: $665.0 million at September 30, 2022 compared to $764.4 million at December 31, 2021.

Research and Development Expenses: Research and development expenses decreased by $38.1 million from $43.0 million for the three months ended September 30, 2021 to $4.9 million for the three months ended September 30, 2022. The decrease in research and development expenses was primarily due to the elimination of the cost share arrangement with Roche, our former COVID-19 program collaborator and includes a credit in the amount of $14.5 million related to the close out by Roche of certain clinical trial activities that were previously the subject of the cost sharing arrangement. Research and development expenses recorded for the Roche cost share agreement for the three months ended September 30, 2021 were $25.3 million compared to a credit of $14.5 million recorded for the three months ended September 30, 2022. Partially offsetting the decrease in research and development expenses was an increase of $1.7 million related to salaries and bonuses, benefits and stock-based compensation expense for our research and development employees and consulting fees and other research and development expenses.

General and Administrative Expenses: General and administrative expenses remained relatively consistent at approximately $11.9 million for the three months ended September 30, 2021 and $11.4 million for the three months ended September 30, 2022.

Interest Income and Other, Net: Interest income and other, net, increased by $4.4 million from less than $0.1 million for the three months ended September 30, 2021 to $4.4 million during the three months ended September 30, 2022. The increase was primarily a result of investing in higher yield marketable securities and higher interest rates.

Income Tax Expense: A net benefit for income taxes of $3.8 million was recorded for the three months ended September 30, 2022 compared to a provision for income taxes of $6.1 million for the three months ended September 30, 2021. The net benefit was primarily the result of changes in estimates between the original provision for 2021 income taxes and the actual amounts reflected in the income tax returns as filed. During 2021, the Company had a tax liability and recorded income tax expense associated with amounts received from our former collaboration with Roche.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Collaboration revenue	$ —	$ 32,811	$ —	$ 159,187
Operating expenses				
Research and development	4,905	43,019	54,396	109,394
General and administrative	11,376	11,939	36,355	32,597

Total operating expenses	16,281	54,958	90,751	141,991
Income (loss) from operations	(16,281)	(22,147)	(90,751)	17,196
Interest income and other, net	4,382	53	5,560	162
Income (loss) before income taxes	(11,899)	(22,094)	(85,191)	17,358
Income tax benefit (expense)	3,833	(6,100)	3,713	(13,300)
Net income (loss)	$ (8,066)	$ (28,194)	$ (81,478)	4,058
Net income (loss) per share attributable to common stockholders				
Basic	$ (0.10)	$ (0.34)	$ (0.98)	$ 0.05
Diluted	$ (0.10)	$ (0.34)	$ (0.98)	$ 0.05
Weighted-average common shares outstanding				
Basic	83,258,537	82,815,636	83,231,146	82,727,268
Diluted	83,258,537	82,815,636	83,231,146	88,462,074

Selected Condensed Consolidated Balance Sheet Data
(in thousands)

	September 30, 2022	December 31, 2021
	(unaudited)	
Cash, cash equivalents, and marketable securities	$ 664,975	$ 764,375
Working capital (1)	666,301	715,520
Total assets	686,576	772,892
Total liabilities	23,389	62,815
Total stockholders' equity	663,187	710,077

(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 September 30, 2022 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 third quarter 2022 financial results and provide a corporate 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. An archived webcast will be available on the Atea website approximately two hours after the event.

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 clinical development of AT-752 for 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.

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