Atea Pharmaceuticals Reports Fourth Quarter and Full Year 2022 Financial Results and Provides Business Update

February 28, 2023

Phase 3 SUNRISE-3 trial evaluating bemnifosbuvir for treatment of COVID-19 in high-risk patients continues enrollment; interim analysis expected in 2H23

Phase 2 trial evaluating combination of bemnifosbuvir and ruzasvir for treatment of HCV to start enrollment in 2Q23; initial results expected by 4Q23

AT-752 dengue program results and update

Conference call at 4:30 pm ET today

BOSTON, Feb. 28, 2023 (GLOBE NEWSWIRE) -- Atea Pharmaceuticals, Inc. (Nasdaq: AVIR) ("Atea"), a clinical-stage biopharmaceutical company, today reported financial results for the fourth quarter and full year ended December 31, 2022 and provided a business update.

"This year, we are poised to continue the meaningful progress made with our clinical development programs following strong execution in 2022," said Jean-Pierre Sommadossi, PhD, Chief Executive Officer and Founder of Atea Pharmaceuticals. "We anticipate several significant clinical milestones for our lead compound, bemnifosbuvir, including an interim analysis from the Phase 3 SUNRISE-3 trial for COVID-19 followed by completion of targeted enrollment by year end. In addition, we plan to initiate patient enrollment in the Phase 2 combination study of bemnifosbuvir and ruzasvir for HCV next quarter, with topline results expected by the end of the year."

"We also have made the business decision to deprioritize the dengue program to focus on COVID-19 and HCV," added Dr. Sommadossi. "We believe AT-752 holds promise for the treatment of dengue as an oral direct acting antiviral. However, it has become clear that improved diagnostics are needed to better identify patients earlier in the course of the disease. In addition, given the high variability in both treatment and prophylaxis settings, substantially larger patient sample sizes would be required for future Phase 2 studies. With the anticipated long clinical timelines and significant associated cost, we will focus our resources on the COVID-19 and HCV programs at this time."

COVID-19 PROGRAM UPDATE

Bemnifosbuvir (AT-527) for COVID-19

SUNRISE-3 Global Phase 3 Registrational Trial of Bemnifosbuvir in High-Risk Non-Hospitalized Patients with COVID-19: Patient enrollment continues in the randomized, double-blind, placebo-controlled, global Phase 3 SUNRISE-3 trial 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 at clinical trial sites planned in the United States, Europe, Japan and rest of the world. Patients are being 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. An interim analysis is expected in the second half of 2023, with anticipated enrollment completion of the targeted 1,500 patients toward the end of 2023.

This trial is comprised of two patient population cohorts derived from the type of SOC received. These are 1) "Supportive Care Population" which will assess bemnifosbuvir as monotherapy (primary analysis) when the patient does not qualify for an authorized oral antiviral treatment or is in a region where oral antivirals are not locally available and 2) "Combination Antiviral Population" which will assess combination therapy being bemnifosbuvir plus SOC if the SOC includes treatment with other 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 both the Supportive Care Population and the Combination Antiviral Population include: COVID-19 complications, medically attended visits, symptom rebound / relapse and viral load rebound.

The patients being enrolled in SUNRISE-3 trial are those at the highest risk for COVID-19 disease progression, consisting of 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.

Favorable Drug Interaction Profile of Bemnifosbuvir Presented at Conference on Retroviruses and Opportunistic Infections (CROI): In February, Atea presented favorable data from three Phase 1 studies of bemnifosbuvir at CROI. Results from a Phase 1 drug-drug interaction (DDI) study in healthy participants administering bemnifosbuvir with midazolam (MDZ), a sensitive CYP3A4 substrate as an index drug, were highlighted in a poster presentation. In addition, results from Phase 1 studies in healthy participants assessing pharmacokinetics with administration of bemnifosbuvir with digoxin (DIG) and rosuvastatin (ROSU) as P-gp and BCRP/OATP1B1 index drugs, respectively, were also presented in a poster at the conference. The results from these studies demonstrated that bemnifosbuvir may be co-administered with a variety of medications that are commonly prescribed among high-risk COVID-19 patients without need for dose modification or discontinuation of the concomitant medication.

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 well suited for combination with bemnifosbuvir for the treatment of COVID-19. Atea has conducted *in vitro* studies examining the combination of bemnifosbuvir with the protease inhibitor nirmatrelvir in an HCoV-229E surrogate model. The results of these studies indicated an additive antiviral effect. These data support the potential activity of the combination of bemnifosbuvir and a protease inhibitor for the treatment of SARS-CoV-2 infection.

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 pharmacokinetic booster (e.g., ritonavir). Compound selection activities are underway in anticipation of filing an investigational new drug application for a clinical candidate around year end 2023.

Hepatitis C Virus (HCV) Program Update

Phase 2 HCV Combination Program: For the treatment of HCV, Atea is advancing the combination of bemnifosbuvir and ruzasvir (RZR), an oral NS5A inhibitor, in Phase 2 development. This combination has a best-in-class profile with the potential to improve the current standard of care by offering a shorter duration, protease inhibitor-free treatment for patients with HCV.

Highly potent antiviral activity of both bemnifosbuvir and RZR administered separately in clinical trials in combination with other drugs for HCV has already been demonstrated. Additionally, Atea has shown in an *in vitro* model that the combination of bemnifosbuvir and RZR had synergistic antiviral effect inhibiting HCV replication.

Regulatory submissions for the initiation of an open label Phase 2 combination study of bemnifosbuvir and RZR are ongoing and dosing of patients in this clinical trial is expected to begin during the second quarter of 2023. Initial data from a lead-in cohort of approximately 60 patients is anticipated in the fourth quarter of 2023.

This open label Phase 2 study is expected to enroll approximately 280 HCV-infected, direct-acting antiviral naive patients across all genotypes, including the 60 patient lead-in cohort. Patients will be administered 550 mg bemnifosbuvir in combination with 180 mg RZR once-daily for eight weeks. 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.

Dengue Program Update

Atea has been a pioneer in the development of an oral antiviral therapeutic for dengue. The proof-of-concept, DEFEND-2, demonstrated that AT-752 treatment led to a faster resolution of fever, the major clinical sign of dengue. However, DEFEND-2 also highlights the need for better diagnostics to identify patients earlier in the course of their disease and a large sample size to account for high patient variability for treatment and prophylaxis. To address these factors, robust Phase 2 studies would require long clinical timelines with major associated costs, which has led to the business decision to deprioritize the dengue program.

DEFEND-2 Results: DEFEND-2 was a randomized, double-blind, placebo-controlled trial evaluating AT-752 750 mg three times a day (TID) or placebo TID for 5 days in dengue endemic countries. The study enrolled adult patients with a positive dengue test (NS1 Ag or PCR) for any one of four known serotypes and fever for no more than 48 hours before study entry. Study objectives included antiviral activity, safety, and pharmacokinetics with a primary endpoint of change in dengue virus viral load from baseline and exploratory endpoints of viremia, NS1 levels, and fever reduction.

Cohort 1 enrolled 21 dengue-infected patients (AT-752 n=14, placebo n=7). Based on their viremia levels at baseline, patients appear to have presented too late in the course of the disease. The primary endpoint of change in dengue viral load was unevaluable since the majority of patients in the placebo arm had viremia levels which were low or below the lower limit of quantification at baseline. Variability in viral kinetics associated with multiple serotypes (1-4) also contributed to the difficulty in evaluating the virologic results. Importantly, platelets were also low at baseline for most patients further highlighting the late clinical presentation. In patients who presented with body temperature above 37°C, the median time to fever resolution was 4 days in the AT-752 arm and greater than 5 days in the placebo arm (prespecified exploratory endpoint). In addition, there was a difference in body temperature change from baseline of 0.9 °C at Day 3 in favor of the AT-752 arm as compared to the placebo arm (post-hoc analysis). Also at Day 3, 100% of patients who presented with baseline body temperature above 37°C had a reduction in body temperature below their baseline levels in the AT-752 arm, versus only 33% of patients in the placebo arm.

In this study, AT-752 demonstrated a favorable safety and tolerability profile with no drug related serious adverse events (SAEs). Two non-drug related SAEs (hospitalizations due to thrombocytopenia and progression to severe dengue) occurred, 1/7 in the placebo arm and 1/14 in the AT-752 arm. Non-serious adverse events were mostly mild or moderate, self-limiting and occurred in comparable frequency in active and placebo arms.

AT-752 Human Challenge Infection Model Study Results: The challenge study was a randomized, placebo-controlled study evaluating healthy subjects who were challenged with a Dengue Virus-1 Live Attenuated Virus strain after receiving AT-752 dosed 750 mg TID or placebo. The results of the study in 5 healthy volunteers were uninterpretable due to the high variability observed in terms of viremia, antigenemia and the onset/severity of symptoms as well as low drug exposures due to lack of dosing compliance. It is anticipated that a larger sample size (n=>50) would be needed in this model to evaluate AT-752 adequately.

Fourth Quarter and Full Year 2022 Financial Results

Cash, Cash Equivalents and Marketable Securities: $646.7 million at December 31, 2022 compared to $764.4 million at December 31, 2021.

Research and Development Expenses: Research and development expenses were $27.5 million and $81.9 million for the fourth quarter and full year 2022, respectively, compared to $57.8 million and $167.2 million for the corresponding periods in 2021. 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. In addition, Atea recorded a $25.0 million expense during the fourth quarter 2021 due to an upfront payment related to the in-license of ruzasvir from Merck. Partially offsetting the decrease in research and development expenses was an increase related to salaries, benefits and stock-based compensation expense for Atea's research and product development employees and consulting fees and other research and development expenses.

General and Administrative Expenses: General and administrative expenses remained relatively consistent at $12.4 million and $48.7 million for the fourth quarter and full year 2022, respectively, compared to $13.2 million and $45.8 million for the corresponding periods in 2021.

Interest Income and Other, Net: Interest income and other, net was $5.6 million and $11.2 million for the fourth quarter and full year 2022, respectively, compared to less than $0.1 million and $0.2 million for the corresponding periods in 2021. The increase was primarily the result of investing in higher yield marketable securities and higher interest rates.

Income Taxes: Income tax expense was $0.1 million and income tax benefit was $3.6 million for the fourth quarter and full year 2022, respectively, compared to income tax expense of $4,100 and $17,400 for the corresponding periods in 2021. The tax benefit for the full year 2022 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, Atea had a tax liability and recorded income tax expense on income resulting from revenue recorded from our former collaboration with Roche.

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

	Three Months Ended December 31,		Year Ended December 31,	
	2022 (unaudited)	2021 (unaudited)	2022 (unaudited)	2021
Collaboration revenue	$ —	$ 192,180	$ —	$ 351,367
Operating expenses				
Research and development	27,540	57,811	81,936	167,205
General and administrative	12,359	13,188	48,714	45,785
Total operating expenses	39,899	70,999	130,650	212,990
Income (loss) from operations	(39,899)	121,181	(130,650)	138,377
Interest income and other, net	5,591	51	11,151	213
Income (loss) before income taxes	(34,308)	121,232	(119,499)	138,590
Income tax benefit (expense)	(123)	(4,100)	3,590	(17,400)
Net income (loss)	$ (34,431)	$ 117,132	$ (115,909)	$ 121,190
Unrealized gain (loss) on available for sale investments	171	—	(684)	—
Comprehensive income (loss)	$ (34,260)	$ 117,132	$ (116,593)	$ 121,190
Net income (loss) per share attributable to common stockholders				
Basic	$ (0.41)	$ 1.41	$ (1.39)	$ 1.46
Diluted	$ (0.41)	$ 1.34	$ (1.39)	$ 1.37
Weighted-average common shares outstanding				
Basic	83,287,639	83,095,320	83,245,385	82,820,037
Diluted	83,287,639	87,092,688	83,245,385	88,249,243

Selected Condensed Consolidated Balance Sheet Data
(in thousands)

	December 31, 2022 (unaudited)	December 31, 2021
Cash, cash equivalents and marketable securities	$ 646,709	$ 764,375
Working capital (1)	642,444	715,520
Total assets	666,708	772,892
Total liabilities	26,136	62,815
Total stockholders' equity	640,572	710,077

(1) Atea defines working capital as current assets less current liabilities. See Atea's consolidated financial statements in its Annual Report on Form 10-K for the year ended December 31, 2022, to be filed February 28, 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 fourth quarter and full year 2022 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. An archived webcast will be available on the Atea website approximately two hours after the event.

About Atea Pharmaceuticals
Atea is a clinical stage biopharmaceutical company focused on discovering, developing and commercializing oral 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 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 the combination of bemnifosbuvir and ruzasvir as a potential treatment for HCV. 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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