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

May 8, 2023

Global Phase 3 SUNRISE-3 trial evaluating bemnifosbuvir for treatment of COVID-19 in high-risk patients continues enrollment; execution of global geographic footprint

Phase 2 trial evaluating combination of bemnifosbuvir and ruzasvir for treatment of HCV on track for first patient dosed 2Q23; initial results expected in 4Q23

Conference call at 4:30 pm ET today

BOSTON, May 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 first quarter ended March 31, 2023 and provided a business update.

"Highlights of the first quarter of 2023 include advancement of our clinical trials and R&D efforts, together with multiple data presentations at several scientific meetings in support of bemnifosbuvir's favorable safety and drug interaction profile and its potential to address the key limitations of current therapies faced by patients with COVID-19 and HCV," said Jean-Pierre Sommadossi, PhD, Chief Executive Officer and Founder of Atea Pharmaceuticals. "The continued execution of the global geographical footprint of our Phase 3 SUNRISE-3 trial for COVID-19 and the recent U.S. Food and Drug Administration Fast Track designation granted to bemnifosbuvir, bring us closer to our goal of delivering an effective treatment to the millions of COVID-19 patients for whom the current standard of care is not a suitable option."

"The initiation of our Phase 2 combination study of bemnifosbuvir and ruzasvir is an important milestone, and we look forward to initial results from our lead-in cohort of approximately 60 patients by year-end," continued Dr. Sommadossi. "Nearly 300,000 people continue to die every year from HCV-related liver diseases, according to the World Health Organization. Our goal, supported by *in vitro* and clinical data generated to-date, 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

Granted Fast Track Designation by U.S. FDA: In April, Atea announced that the U.S. Food and Drug Administration (FDA) granted Fast Track designation to 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.

Bemnifosbuvir SUNRISE-3 trial in High-Risk Outpatients with COVID-19: Patient enrollment continues in the global, randomized, double-blind, placebo-controlled, registrational Phase 3 SUNRISE-3 trial evaluating bemnifosbuvir, a nucleotide polymerase inhibitor, administered concurrently with locally available standard of care. The study is designed to enroll at least 1,500 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 locally available standard of care and either bemnifosbuvir 550 mg twice-daily (BID) or placebo BID for five days. The primary endpoint of the study is all-cause hospitalization or death through Day 29 in the supportive care population comprised of at least 1,300 patients.

Presentation of Bemnifosbuvir Data Showing Reduced Hospitalizations for COVID-19 Patients at 2023 European Congress of Clinical Microbiology & Infectious Diseases (ECCMID 2023): In April, 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.

Favorable Drug Interaction Profile of Bemnifosbuvir Presented at 36th International Conference on Antiviral Research (ICAR 2023): In March, Atea presented Phase 1, *in vitro* and preclinical data that demonstrated key profile attributes of bemnifosbuvir. The data presented included results from a Phase 1 human absorption, distribution, metabolism, and excretion (ADME) study for bemnifosbuvir demonstrating a favorable ADME profile supportive of the dosing regimen being evaluated in SUNRISE-3. *In vitro* metabolism and transporter interaction studies showed bemnifosbuvir has a low risk for interactions with medicines commonly taken by COVID-19 high risk patients for other conditions. *In vitro* studies also demonstrated advantages of bemnifosbuvir's mechanism of action, which targets conserved regions of the virus that causes COVID-19. These potential advantages include a high barrier to resistance and maintenance of antiviral activity in the presence of COVID-19 variants.

Favorable Profile of Bemnifosbuvir Related to Low Risk for Drug-Drug Interactions Presented at Conference on Retroviruses and Opportunistic Infections (CROI 2023): In February, Atea presented data from three Phase 1 studies that showed the favorable drug-drug interaction profile of bemnifosbuvir. The results of these studies, including a study with midazolam, indicate that no dosage adjustment of CYP3A substrates or of drugs that are sensitive substrates of efflux and hepatic uptake transporters is likely to be needed when co-administrated with bemnifosbuvir. CYP3A is an enzyme that metabolizes many classes of medicines and medicinal supplements, and efflux/hepatic uptake transporters regulate cellular

trafficking of many medicines that are commonly prescribed to COVID-19 high risk patients.

Bemnifosbuvir Retains Antiviral Activity Against Omicron Subvariant XBB *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 subvariant XBB. 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, BA.2, BA.4, and BA.5.

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: Atea is on track to initiate patient dosing in the second quarter of 2023 in the Phase 2 combination study of bemnifosbuvir and ruzasvir, an oral NS5A inhibitor.

This open label Phase 2 study is expected to enroll approximately 280 HCV-infected, direct-acting antiviral naive patients across all genotypes, including a 60 patient lead-in cohort. Patients will be administered 550 mg bemnifosbuvir in combination with 180 mg ruzasvir 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. Initial data from the 60-patient lead-in cohort is anticipated in the fourth quarter of 2023.

Synergistic Antiviral Effect Observed for the Combination of Bemnifosbuvir + Ruzasvir Against HCV *In Vitro* Presented at 36th International Conference on Antiviral Research (ICAR 2023): In March, Atea presented *in vitro* data demonstrating that the combination of bemnifosbuvir and ruzasvir had greater inhibition of HCV replication than the sum of both compounds alone, suggesting a synergistic antiviral effect when bemnifosbuvir and ruzasvir were administered together.

In vivo results from a 13-week toxicity study in rats also demonstrated that systemic exposures of bemnifosbuvir, its metabolites, and ruzasvir were similar when administered independently or in combination, suggesting no significant drug-drug interactions between bemnifosbuvir and ruzasvir.

This synergistic activity and no significant drug-drug interactions, together with the previously demonstrated potent, pan-genotypic, antiviral activity of each agent alone, support the initiation of the Phase 2 combination of bemnifosbuvir and ruzasvir, which has the potential to offer a differentiated, short duration, pan-genotypic, protease inhibitor-sparing regimen for patients with HCV, with or without cirrhosis.

New *In Vitro* Bemnifosbuvir and Ruzasvir Data: New data from an *in vitro* study demonstrated that bemnifosbuvir is at least 10 times more potent than sofosbuvir and retains full potency against all HCV GT-1a and GT-3a NS5A resistance associated variants (RAVs) tested. In addition, new data show that ruzasvir is more potent than velpatasvir and retains a favorable potency profile against a panel of HCV GT-1a and GT-3a NS5A RAVs. Based on these *in vitro* data combined with other data to-date, it is expected that the combination of bemnifosbuvir and ruzasvir will retain antiviral activity against major clinically relevant HCV NS5A RAVs.

Dengue Program Update

Data presented at ECCMID 2023, and recently published in the peer-reviewed journal, *Antiviral Research,* together with data to-date, indicate a favorable biological, pharmacological and safety profile for AT-752. However, due to the anticipated long clinical timelines and major associated costs, Atea deprioritized its dengue program and the development of AT-752 in February 2023 and made the business decision to focus on its COVID-19 and HCV programs.

First Quarter 2023 Financial Results

Cash, Cash Equivalents and Marketable Securities: $620.5 million at March 31, 2023 compared to $646.7 million at December 31, 2022.

Research and Development Expenses: Research and development expenses remained relatively consistent at $29.0 million for the quarter ended March 31, 2023 compared to $29.6 million for the quarter ended March 31, 2022.

General and Administrative Expenses: General and administrative expenses remained relatively consistent at $12.6 million for the quarter ended March 31, 2023 compared to $12.5 million for the quarter ended March 31, 2022.

Interest Income and Other, Net: Interest income and other, net was $6.3 million for the quarter ended March 31, 2023 compared to $0.1 million for the quarter ended March 31, 2022. The increase was primarily the result of investing in higher yield marketable securities and higher interest rates.

Income Taxes: Income tax expense was $0.2 million for the quarter ended March 31, 2023. Atea did not record income tax expense for the quarter ended March 31, 2022.

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

	Three Months Ended March 31,	
	2023	**2022**
Operating expenses:		
Research and development	$ 28,954	$ 29,633

General and administrative	12,615	12,542
Total operating expenses	41,569	42,175
Loss from operations	(41,569)	(42,175)
Interest income and other, net	6,299	98
Loss before income taxes	(35,270)	(42,077)
Income tax expense	(197)	—
Net loss	$ (35,467)	$ (42,077)
Other comprehensive income:		
Unrealized gains on available-for-sale	377	
Comprehensive loss	$ (35,090)	$ (42,077)
Net loss per share – basic and diluted	$ (0.43)	$ (0.51)
Weighted-average common shares used in computing net loss per share – basic and diluted	83,332,397	83,176,408

Selected Condensed Consolidated Balance Sheet Data
(in thousands)

	March 31, 2023	December 31, 2022
	(unaudited)	
Cash, cash equivalents, and marketable securities	$ 620,488	$ 646,709
Working capital[(1)]	620,029	642,444
Total assets	638,131	666,708
Total liabilities	19,949	26,136
Total stockholders' equity	618,182	640,572

(1) Atea 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 March 31, 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 first 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 copy of the audio 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 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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