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

August 8, 2022

Advancing Bemnifosbuvir to Late-Stage Development for COVID-19 Following Meetings with U.S. Food and Drug Administration (FDA) and European Medicines Agency (EMA) Emergency Task Force

New Data Demonstrate Bemnifosbuvir Retained Antiviral Activity Against Omicron Subvariant In Vitro

Progressing Internal Second-Generation Protease Inhibitor Discovery Program for COVID-19 Combination Therapy; New Data Indicate Additive Antiviral Effect with Bemnifosbuvir in Combination with Nirmatrelvir (Protease Inhibitor) In Vitro

Enrolling AT-752 Global Phase 2 Trial and U.S. Human Challenge Study for Dengue

Preparing for Initiation of Phase 2 Combination Trial of Bemnifosbuvir and Ruzasvir for Hepatitis C (HCV)

Conference Call at 4:30 pm ET Today

BOSTON, Aug. 08, 2022 (GLOBE NEWSWIRE) -- Atea Pharmaceuticals, Inc. (Nasdaq: AVIR) ("Atea"), a clinical-stage biopharmaceutical company, today reported financial results for the second quarter ended June 30, 2022 and provided a business update.

"COVID-19 continues to be a global emergency with waning efficacy from vaccines, therapeutics and prior infections driving an unmet medical need. New antivirals with improved profiles are urgently needed," said Jean-Pierre Sommadossi, PhD, Chief Executive Officer and Founder of Atea Pharmaceuticals. "We are in the process of quickly finalizing a global late-stage trial protocol for bemnifosbuvir for COVID-19 following meetings with the FDA and EMA's Emergency Task Force. Our goal is to initiate a global late-stage trial in the fourth quarter of 2022. As part of a multipronged approach for COVID-19, we also 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 identify a clinical candidate later this year."

"For dengue, we are currently enrolling two proof-of-concept trials for AT-752 and expect initial results in late 2022. Dengue is the most prevalent mosquito-borne virus with no approved antiviral therapies, and it is a substantial public health and economic burden. Additionally, for HCV we are preparing for the initiation of a Phase 2 combination study of bemnifosbuvir and ruzasvir, which is expected in late 2022. The target profile of our HCV combination includes convenient and short duration treatment with the potential for the first ribavirin-free therapy for decompensated disease," continued Dr. Sommadossi. "Importantly, we remain well capitalized to advance our programs, which we expect will deliver a number of important milestones over the next 18 months."

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

Bemnifosbuvir to Advance to Late-Stage Development for COVID-19: In July, Atea had an End-of-Phase 2 meeting with the FDA and met with the EMA Emergency Task Force to discuss bemnifosbuvir's program to-date and the design of a global late-stage clinical trial for the treatment of mild-to-moderate COVID-19. The trial will focus on high-risk patients, including those who are immunocompromised, and patients will be enrolled regardless of vaccination status. The primary endpoint of the study will be hospitalization and death. The study will evaluate bemnifosbuvir 550 mg twice-daily (BID) for five days. Operational planning for this trial is currently underway with the goal of initiation during the fourth quarter of 2022.

Topline Efficacy Results from Phase 3 MORNINGSKY Trial: In May, Atea reported a topline analysis of data from the MORNINGSKY trial in which the primary endpoint, time to symptom alleviation, was not achieved. However, a 71% reduction in hospitalization (2.9% versus 10%) was observed (p=0.047, unadjusted, exploratory) in the bemnifosbuvir arm (n=137) versus placebo (n=70). There were no deaths in the trial. Hospitalization and death are study endpoints that are currently preferred by the FDA and other regulatory authorities.

MORNINGSKY was a randomized, double-blind, multi-center, placebo-controlled Phase 3 trial evaluating the efficacy, safety, antiviral activity, and pharmacokinetics of bemnifosbuvir, which intended to enroll up to 1,400 patients randomized 2:1 to receive bemnifosbuvir 550 mg BID or placebo in an outpatient setting. Consistent with previous studies, bemnifosbuvir 550 mg BID was generally safe and well tolerated with no drug-related serious adverse events. The study was closed out early in December 2021, having enrolled 216 patients of which 207 were evaluable for efficacy.

Data from Final Analysis of Phase 2 Hospitalized Study in High-Risk Patients: In May, Atea reported final clinical results from the Phase 2 hospitalized study in high-risk patients (n=83) and results suggest potential clinical benefits. The global Phase 2 trial was a randomized, double-blind, placebo-controlled, multi-center study to evaluate bemnifosbuvir in patients with moderate COVID-19 in the hospital setting. There were 3 deaths in the study, no deaths were reported in patients treated with bemnifosbuvir versus 3 deaths reported with placebo. Final virology results (secondary endpoint) were consistent with previously reported interim data from this study. Bemnifosbuvir was generally safe and well tolerated with no drug-related serious adverse events.

New: Bemnifosbuvir Retains Antiviral Activity Against Omicron Subvariant *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 variant Omicron BA.2. AT-511 has previously demonstrated *in vitro* potent antiviral activity against variants of concern and/or of interest, including Alpha, Beta, Gamma, Epsilon, Delta and Omicron BA.1.

Advancing a Multipronged Approach for COVID-19 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 well suited for combination therapy with bemnifosbuvir. As part of this effort, Atea's target profile is a protease inhibitor that is highly potent, has a good safety profile with limited drug-drug interactions and does not require a booster (e.g., ritonavir). The optimization of lead compounds is ongoing with a target of late 2022 for selection of a clinical candidate.

New: Additive Antiviral Effect Demonstrated with Bemnifosbuvir in Combination with Protease Inhibitor *In Vitro* in a Surrogate Virus Model: The combination of bemnifosbuvir with the protease inhibitor nirmatrelvir was examined *in vitro* in an HCoV-229E surrogate model and results indicate 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

Enrolling Global Phase 2 Dengue Study and Human Challenge Trial: Patient enrollment continues for the global Phase 2 DEFEND-2 (**DE**ngue **F**ever **END**) study of AT-752 for the treatment of dengue. The randomized, double-blind, placebo-controlled study is evaluating multiple doses of AT-752 and is expected to enroll up to 60 adult patients infected with dengue. The primary objective of the study is to assess antiviral activity, with change from baseline in 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 study, 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.

Results from the human challenge trial and initial results from the DEFEND-2 study are expected in the fourth quarter of 2022.

Hepatitis C Virus (HCV) Program Update

Phase 2 HCV Combination Program: Atea has completed a required combination preclinical toxicology study and is currently manufacturing ruzasvir (RZR) clinical trial supplies. Also, Atea is finalizing a clinical trial design for the Phase 2 combination study of bemnifosbuvir and RZR, which is expected to be initiated in late 2022. 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.

Second Quarter 2022 Financial Results

Cash and Cash Equivalents: $684.5 million at June 30, 2022 compared to $764.4 million at December 31, 2021.

Research and Development Expenses: Research and development expenses for the quarter ended June 30, 2022 in the amount of $19.9 million decreased by $19.9 million from $39.8 million for the quarter ended June 30, 2021. The decrease in research and development expenses was primarily due to the elimination of the cost share arrangement with Roche, our former collaborator, on the COVID-19 program.

General and Administrative Expenses: General and administrative expenses for the quarter ended June 30, 2022 in the amount of $12.4 million increased by $0.5 million from $11.9 million for the quarter ended June 30, 2021. The increase in general and administrative expenses was primarily due to the expansion of our organization.

Interest Income and Other, Net: Interest income and other, net increased by $1.0 million for quarter ended June 30, 2022 as a result of higher returns earned on cash and cash equivalents.

Income Tax Expense: Income tax expense decreased by $7.1 million for the three months ended June 30, 2022 as the company previously had a tax liability associated with amounts received from our former collaboration with Roche.

Net Income (Loss): Net loss for the quarter ended June 30, 2022 was $31.3 million compared to net income of $1.5 million for the quarter ended June 30, 2021. The net loss for the quarter ended June 30, 2022 as compared to net income for the quarter ended June 30, 2021 resulted principally from a decrease in revenue of $60.4 million as a result of the termination of the Roche agreement offset by changes in operating expenses, interest income and income taxes noted above.

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,	
	2022	2021	2022	2021
Collaboration revenue	$ —	$ 60,391	$ —	$ 126,376
Operating expenses				
Research and development	19,858	39,803	49,491	66,375
General and administrative	12,437	11,901	24,979	20,658
Total operating expenses	32,295	51,704	74,470	87,033
Income (loss) from operations	(32,295)	8,687	(74,470)	39,343
Interest income and other, net	1,080	52	1,178	109

Income (loss) before income taxes	(31,215)	8,739	(73,292)	39,452
Income tax expense	(120)	(7,200)	(120)	(7,200)
Net income (loss) and comprehensive income (loss)	$ (31,335)	$ 1,539	$ (73,412)	$ 32,252
Net income (loss) per share attributable to common stockholders				
Basic	$ (0.38)	$ 0.02	$ (0.88)	$ 0.39
Diluted	$ (0.38)	$ 0.02	$ (0.88)	$ 0.36
Weighted-average common shares outstanding				
Basic	83,257,591	82,743,530	83,217,223	82,662,019
Diluted	83,257,591	88,091,384	83,217,223	88,683,767

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

	June 30, 2022	December 31, 2021
Cash and cash equivalents	$ 684,480	$ 764,375
Working capital(1)	664,344	715,520
Total assets	694,338	772,892
Total liabilities	33,881	62,815
Total stockholders' equity	660,457	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 June 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 second 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, https://ir.ateapharma.com/news-and-events/events-and-presentations. An archived webcast will be available on the Atea website approximately two hours after the event.

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 severe diseases. 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 severe 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 difficult-to-treat, severe viral infections, including severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), the virus that causes COVID-19, hepatitis C virus (HCV), dengue virus 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, including bemnifosbuvir, 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. 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.

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