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

May 10, 2022

New clinical results from MORNINGSKY trial shows 71% reduction in hospitalization (secondary endpoint) in broad patient population with COVID-19 treated with bemnifosbuvir (AT-527) versus placebo (p=0.047, unadjusted, exploratory)

New clinical results from final analysis of Phase 2 hospitalized study in high-risk COVID-19 patients suggest potential clinical benefits with bemnifosbuvir versus placebo

New in vitro results demonstrate bemnifosbuvir retains antiviral activity against all SARS-CoV-2 variants of concern, including Omicron (BA.1)

Initiated Phase 2 global study and human challenge trial with AT-752 as potential first-in-class antiviral treatment for dengue

On track to initiate Phase 2 combination study of bemnifosbuvir and ruzasvir (RZR) for hepatitis C virus (HCV) in 2H 2022

Conference call at 8:00 am ET today

BOSTON, May 10, 2022 (GLOBE NEWSWIRE) -- Atea Pharmaceuticals, Inc. (Nasdaq: AVIR) (“Atea”), a clinical-stage biopharmaceutical company, today reported financial results for the first quarter ended March 31, 2022 and provided a business update.

“We are very pleased to report new bemnifosbuvir data, showing for the first time, clinical benefits in two placebo-controlled trials, which were recently closed out. These new results show a meaningful reduction in hospitalization in a broad patient population treated in the MORNINGSKY outpatient trial and suggest potential clinical benefits in the Phase 2 high-risk hospitalized trial. In addition, new *in vitro* data demonstrate the broad antiviral activity of bemnifosbuvir across variants of concern, including Omicron,” said Jean-Pierre Sommadossi, PhD, Chief Executive Officer and Founder of Atea Pharmaceuticals. “With the bemnifosbuvir results to-date, including clinical benefits, favorable safety and tolerability data, we are pursuing interactions with regulatory authorities to review our data package and to discuss the next steps in our COVID-19 clinical development program.”

“Beyond COVID-19, we have made significant progress across our other pipeline programs, including initiation of a global Phase 2 study and a human challenge trial advancing AT-752 as a potential first antiviral treatment for dengue fever, the most prevalent mosquito-borne viral disease with a large global disease burden. Additionally, we continue preparations for the initiation of our upcoming Phase 2 study in HCV evaluating the combination of bemnifosbuvir and ruzasvir,” continued Dr. Sommadossi. “The progress we are making today sets the stage for a number of important milestones over the next 18 months. Importantly, we remain well capitalized to advance the clinical development of these product candidates in our effort to provide new medicines to patients with severe viral diseases.”

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

New Topline Efficacy Results from MORNINGSKY Trial: In a topline analysis of data from the MORNINGSKY trial, 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 U.S. Food and Drug Administration and other regulatory authorities.

The study enrolled a broad patient population of whom approximately 50% were high risk and 50% were standard risk; 28% of patients were vaccinated; and 56% were seropositive at baseline. Consistent with previous studies, bemnifosbuvir 550 mg twice-daily (BID) was generally safe and well tolerated. There were no drug-related serious adverse events. Adverse events leading to treatment discontinuation were 3% for bemnifosbuvir versus 7% for placebo and there were no gastrointestinal-related events leading to treatment discontinuation.

MORNINGSKY was a randomized, double-blind, multi-center, placebo-controlled Phase 3 trial evaluating the efficacy, safety, antiviral activity, and pharmacokinetics of bemnifosbuvir in up to 1,400 patients randomized 2:1 to receive bemnifosbuvir 550 mg BID or placebo in an outpatient setting. As previously announced, the study was closed out early in December 2021, having enrolled 216 patients of which 207 were evaluable for efficacy. Atea plans to present the full results of this study at an upcoming scientific meeting.

New Data from Final Analysis of Phase 2 Hospitalized Study in High-Risk Patients: Final clinical results from the Phase 2 hospitalized study in high-risk patients (n=83) suggest potential clinical benefits. The overall rate of disease progression was low, which had an impact on the ability to assess the primary endpoint of progression of respiratory insufficiency (PRI) rate. The results showed a 7.5% PRI rate for bemnifosbuvir 550 mg BID versus a 10% PRI rate for placebo (primary endpoint). The respiratory events associated with progression were less severe in the bemnifosbuvir treated patients as compared to those receiving placebo. 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 and no adverse events leading to treatment discontinuation.

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. The key inclusion criteria for this study were adult patients 18 years or older with risk factors such as obesity, diabetes, asthma and hypertension. Study objectives were to assess safety, tolerability, clinical and antiviral efficacy. Patients were randomized within five days of symptom onset to receive either bemnifosbuvir (550 mg BID in Part A; 1100 mg BID in Part B) or placebo for five days. In total, 81 patients

were randomized in Part A (41 patients in the 550 mg BID arm; 40 patients in placebo arm) and 2 patients were randomized in Part B (0 patients in 1100 mg BID arm; 2 patients in placebo arm). The evolving nature of the standard of care resulted in the in the early close out of the study which limited the Part B enrollment. Atea plans to present the full results of this study at an upcoming scientific meeting.

Next Steps for Bemnifosbuvir Clinical Development for COVID-19: In light of the new MORNINGSKY outpatient data and the final analysis of the Phase 2 hospitalized study, Atea is pursuing interactions with regulatory authorities to review the data package and to discuss the next steps in the bemnifosbuvir clinical development program for COVID-19.

New *In Vitro* Results: AT-511, the free base of bemnifosbuvir, has been shown to be a potent inhibitor of SARS-CoV-2 *in vitro*. New results demonstrate bemnifosbuvir retained potent antiviral activity against the SARS-CoV-2 variant Omicron (BA.1). *In vitro* results evaluating antiviral activity against all variants of concern and/or of interest have previously included Alpha, Gamma, Epsilon, Delta.

Publication of Bemnifosbuvir Mechanism Data in Peer-Reviewed Journal: In February 2022, data highlighting bemnifosbuvir's unique dual target mechanism of action consisting of chain termination (RdRp) and nucleotityltransferase (NiRAN) inhibition were published in the peer-reviewed journal *Nature Communications*.

Nonclinical Bemnifosbuvir Toxicology Data at Society of Toxicology (SOT) 61st Annual Meeting: Atea's poster presentation, which evidenced a favorable overall nonclinical safety profile for bemnifosbuvir, including lack of reproductive and development toxicity in animal models, was selected by the SOT Risk Assessment Specialty Selection Executive Committee as a top ten abstract this year.

AT-752 Program Update for Dengue

Initiated Phase 2 Dengue Fever Study and Human Challenge Trial: Atea has initiated 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 will evaluate multiple doses of AT-752 and enroll up to 60 adult patients infected with dengue. The primary objective of the study is to evaluate 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 has initiated 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 are expected in the fourth quarter of 2022 and initial results from the DEFEND-2 study are expected in late 2022.

Hepatitis C Virus (HCV) Program Update

Phase 2 HCV Combination Program: In January 2022, Atea announced that it had obtained exclusive worldwide rights to develop, manufacture and commercialize ruzasvir (RZR), an oral NS5A inhibitor, through a license agreement with Merck. Atea is currently manufacturing clinical trial supply of RZR and is evaluating clinical trial designs for the Phase 2 combination study of bemnifosbuvir and RZR, which is expected to be initiated in the second half of 2022. Studies conducted by Atea have shown *in vitro* synergy of the combination of bemnifosbuvir and RZR in inhibiting HCV replication.

First Quarter 2022 Financial Results

Cash and Cash Equivalents: $705.5 million at March 31, 2022 compared to $764.4 million at December 31, 2021. In the quarter ended March 31, 2022, cash expenditures included payment of amounts previously recorded as accrued expenses, including a payment to Merck in the amount of $25 million in connection with the license of ruzasvir and a payment in the amount of $10.4 million in connection with the cost share arrangement with Roche.

Research and Development Expenses: Research and development expenses for the quarter ended March 31, 2022 in the amount of $29.6 million increased by $3.0 million from $26.6 million for the quarter ended March 31, 2021. The increase in research and development expenses was primarily due to the expansion of our organization and reflected an increase in payroll and personnel-related expenses, including salaries, benefits and stock-based compensation expense offset by a decrease in external research and development expenses.

General and Administrative Expenses: General and administrative expenses for the quarter ended March 31, 2022 in the amount of $12.5 million increased by $3.7 million from $8.8 million for the quarter ended March 31, 2021. The increase in general and administrative expenses was primarily due to the expansion of our organization and reflected an increase in payroll and personnel-related expenses, including salaries, benefits and stock-based compensation expense and other general and administrative expenses.

Net Income (Loss): Net loss for the quarter ended March 31, 2022 was $42.1 million compared to net income of $30.7 million for the quarter ended March 31, 2021. The net loss for the quarter ended March 31, 2022 as compared to net income for the quarter ended March 31, 2021 resulted principally from a decrease in revenue of $66.0 million as a result of the termination of the Roche collaboration and an increase of $6.7 million in operating expenses noted above.

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

	Three Months Ended March 31,	
	2022	**2021**
Collaboration revenue	$ —	$ 65,985
Operating expenses		
Research and development	29,633	26,571
General and administrative	12,542	8,759

Total operating expenses	42,175	35,330
Income (loss) from operations	(42,175)	30,655
Interest income and other, net	98	58
Income (loss) before income taxes	(42,077)	30,713
Income tax expense	—	—
Net income (loss) and comprehensive income (loss)	$ (42,077)	$ 30,713
Net income (loss) per share attributable to common stockholders		
Basic	$ (0.51)	$ 0.37
Diluted	$ (0.51)	$ 0.34
Weighted-average common shares outstanding		
Basic	83,176,408	82,577,836
Diluted	83,176,408	89,099,075

Selected Condensed Consolidated Balance Sheet Data
(in thousands, except share and per share amounts)

	March 31, 2022	December 31, 2021
	(unaudited)	
Cash and cash equivalents	$ 705,545	$ 764,375
Working capital(1)	684,622	715,520
Total assets	717,189	772,892
Total liabilities	37,305	62,815
Total stockholders' equity	679,884	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 March 31, 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 first quarter 2022 financial results and provide a corporate update today at 8 a.m. ET. To access the live conference call, please dial (800) 343-5172 (domestic) or (203) 518-9814 (international) at least five minutes prior to the start time and refer to conference ID: AVIRQ122. 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 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, life-threatening 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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