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

November 8, 2023

Patient enrollment continues in global Phase 3 SUNRISE-3 trial evaluating bemnifosbuvir for COVID-19; first interim analysis expected 1Q24

Phase 2 bemnifosbuvir and ruzasvir combination trial for hepatitis C (HCV) advances, initial results from 60-patient lead-in cohort expected 1Q24

Conference call at 4:30 pm ET today

BOSTON, Nov. 08, 2023 (GLOBE NEWSWIRE) -- Atea Pharmaceuticals, Inc. (Nasdaq: AVIR) (“Atea” or the “Company”), 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 third quarter ended September 30, 2023 and provided a business update.

“Promising enrollment trends continue in our Phase 3 SUNRISE-3 trial for COVID-19, reflecting infection rates globally. Our goal is to deliver an effective treatment to the millions of patients for whom the current standard of care is not a suitable option, and we look forward to reporting on several milestones for SUNRISE-3 in 2024," said Jean-Pierre Sommadossi, PhD, Chief Executive Officer and Founder of Atea Pharmaceuticals. “The SARS-CoV-2 virus continues to mutate faster than other endemic RNA viruses, and we need new, safe, and well tolerated oral antivirals for all patients, including those who are the most vulnerable. To avoid the emergence of cross-resistance, we also need a broader and more diversified arsenal of oral antivirals with various distinct mechanisms of action.”

"We are pleased with the substantial progress achieved in our Phase 2 combination study of bemnifosbuvir and ruzasvir for the treatment of HCV. We’ve quickly completed enrollment of the 60-patient lead-in cohort and initial results are expected in early 2024," continued Dr. Sommadossi. "Our goal for this program is to substantially improve the current standard of care by offering a short, pan-genotypic, protease inhibitor-free treatment option for HCV patients. Despite available treatment options, there remains a large, underserved HCV patient population that continues to grow dramatically due to the opioid crisis, injection drug use and HCV reinfection."

Bemnifosbuvir for COVID-19

In April 2023, Fast Track designation, which may facilitate expedited development and review processes, was granted by the U.S. Food and Drug Administration (FDA) to the evaluation of bemnifosbuvir for the treatment of COVID-19.

Bemnifosbuvir SUNRISE-3 Trial in High-Risk Outpatients with COVID-19: Patient enrollment continues in the global, multicenter, randomized, double-blind, placebo-controlled, registrational Phase 3 SUNRISE-3 trial evaluating bemnifosbuvir, a nucleotide polymerase inhibitor, or placebo administered concurrently with locally available standard of care (SOC). SUNRISE-3 is targeting approximately 300 clinical sites in up to 30 countries, enrolling high-risk outpatients with mild or moderate COVID-19, including those in the U.S., Europe, and Japan. Patients are randomized 1:1 to receive bemnifosbuvir 550 mg twice-daily (BID) or placebo BID for five days. The trial comprises two study populations based on the type of SOC received: 1) the "supportive care population," evaluating bemnifosbuvir as monotherapy (primary analysis), and 2) the "combination antiviral population," assessing combination therapy if the SOC includes other compatible antiviral drugs against COVID-19 (secondary analysis).

The SUNRISE-3 patient population will include those aged ≥70 years (regardless of other risk factors), individuals aged ≥55 years with one or more risk factors, those aged ≥50 years with two or more risk factors, and individuals aged ≥18 years with specific risk factors, including immunocompromised conditions, irrespective of COVID-19 vaccination status. Additionally, patients with reduced renal function will be eligible for enrollment.

The primary endpoint of the SUNRISE-3 study is all-cause hospitalization or death through Day 29 in the supportive care (monotherapy) arm. The trial includes two interim analyses to assess safety and futility, conducted after approximately 650 and 1,350 evaluable patients, respectively, in the supportive care (monotherapy) arm. Currently, Atea anticipates providing an update after each of these interim analyses are completed with the first update expected to occur in the first quarter of 2024.

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 identification 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: Enrollment has been completed for the 60-patient lead-in cohort for the Phase 2 open-label study evaluating bemnifosbuvir in combination with ruzasvir in treatment-naïve HCV-infected patients, either without cirrhosis or with compensated cirrhosis. This study aims to assess the safety and efficacy of eight weeks of treatment with the pan-genotypic combination, consisting of once-daily bemnifosbuvir 550 mg and ruzasvir 180 mg. A total of approximately 280 treatment-naïve HCV-infected patients are anticipated to be enrolled across all genotypes, including the 60-patient lead-in cohort. Primary endpoints include safety and sustained virologic response (SVR) at Week 12 post-treatment. Other virologic endpoints encompass virologic failure, SVR at Week 24 post-treatment, and resistance. Preliminary data from the 60-patient lead-in cohort are expected to become available and to be reported by Atea during the first quarter of 2024.

The combination of bemnifosbuvir and ruzasvir has the potential to significantly enhance the current standard of care by offering a differentiated short duration, pan-genotypic, protease-inhibitor-free regimen for HCV-infected patients with or without cirrhosis.

Third Quarter 2023 Financial Results

Cash, Cash Equivalents and Marketable Securities: $595.1 million at September 30, 2023 compared to $608.1 million at June 30, 2023.

Research and Development Expenses: Research and development expenses for the quarter ended September 30, 2023 in the amount of $28.2 million increased by $23.3 million from $4.9 million for the quarter ended September 30, 2022. The increase was primarily driven by higher external spend related to our Phase 3 COVID-19 SUNRISE-3 clinical trial and our Phase 2 clinical trial of the combination of bemnifosbuvir and ruzasvir for the treatment of HCV. For the three months ended September 30, 2022, we recorded a reduction in research and development expense of $14.6 million related to a credit received from Roche compared to a credit of $3.7 million for the three months ended September 30, 2023.

General and Administrative Expenses: General and administrative expenses for the quarter ended September 30, 2023 in the amount of $12.6 million increased by $1.2 million from $11.4 million for the quarter ended September 30, 2022. The increase was primarily the result of higher stock-based compensation and professional fees.

Interest Income and Other, Net: Interest income and other, net was $7.9 million for the quarter ended September 30, 2023 compared to $4.4 million for the quarter ended September 30, 2022. The increase was primarily the result of investing in higher yield marketable securities and higher interest rates.

Income Tax Expense: Income tax expense was $0.2 million for the quarter ended September 30, 2023 compared to a benefit of $3.8 million for the quarter ended September 30, 2022. The net benefit recorded for the three months ended September 30, 2022 was primarily the result of changes in estimates between our original provision for 2021 income taxes and the actual amounts reflected in the income tax returns as filed.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	**2022**	**2023**	**2022**
Operating expenses				
Research and development	$ 28,181	$ 4,905	$ 79,198	$ 54,396
General and administrative	12,604	11,376	38,391	36,355
Total operating expenses	40,785	16,281	117,589	90,751
Loss from operations	(40,785)	(16,281)	(117,589)	(90,751)
Interest income and other, net	7,864	4,382	21,466	5,560
Loss before income taxes	(32,921)	(11,899)	(96,123)	(85,191)
Income tax benefit (expense)	(221)	3,833	(669)	3,713
Net loss	$ (33,142)	$ (8,066)	$ (96,792)	$ (81,478)
Other comprehensive income (loss):				
Unrealized gain (loss) on available-for- sale investments	48	(855)	422	(855)
Comprehensive loss	$ (33,094)	$ (8,921)	$ (96,370)	$ 82,333
Net loss per share – basic and diluted	$ (0.40)	$ (0.10)	$ (1.16)	$ (0.98)
Weighted-average common shares used in computing net loss per share – basic and diluted	83,399,769	83,258,537	83,374,328	83,231,146

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

	September 30, 2023	**December 31, 2022**
Cash, cash equivalents and marketable securities	$ 595,126	$ 646,709
Working capital(1)	584,423	642,444
Total assets	608,075	666,708
Total liabilities	26,345	26,136
Total stockholders' equity	581,730	640,572

(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, 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 the third 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 webcast will be available on the Atea website approximately two hours after the event.

About Bemnifosbuvir for COVID-19

Bemnifosbuvir, a nucleotide polymerase inhibitor, targets the SARS-CoV-2 RNA polymerase (nsp12), a highly conserved gene that is unlikely to change as the virus mutates and new variants continue to emerge. This gene is responsible for both replication and transcription of SARS-CoV-2. Bemnifosbuvir has a unique mechanism of action, with dual targets consisting of chain termination (RdRp) and nucleotityltransferase (NiRAN) inhibition, which has the potential to create a high barrier to resistance. *In vitro* data confirmed that bemnifosbuvir is active with similar efficacy against all variants of concern and variants of interest that have been tested, including Omicron subvariants BA.4, BA.5 and XBB.

About Bemnifosbuvir and Ruzasvir for Hepatitis C Virus (HCV)

Bemnifosbuvir has been shown to be approximately 10-fold more active than sofosbuvir (SOF) *in vitro* against a panel of laboratory strains and clinical isolates of HCV genotypes 1–5. *In vitro* studies demonstrated bemnifosbuvir remained fully active against SOF resistance-associated strains (S282T), with up to 58-fold more potency than SOF. The pharmacokinetic (PK) profile of bemnifosbuvir supports once-daily dosing for the treatment of HCV and bemnifosbuvir has been well-tolerated at doses up to 550 mg for durations up to 8-12 weeks in healthy and HCV-infected subjects.

RZR, an oral NS5A inhibitor, has demonstrated highly potent and pan-genotypic antiviral activity in preclinical (picomolar range) and clinical studies. RZR has been administered to over 1,200 HCV-infected patients at daily doses of up to 180 mg for 12 weeks and has demonstrated a favorable safety profile. RZR's PK profile supports once-daily dosing.

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 includes "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements in this press release include but are not limited to the date and time of the Company's presentation at the conference and the webcast of the presentation. When used herein, words including "expects," "may," "will," "anticipates," "plans", and similar expressions are intended to identify forward-looking statements. In addition, any statements or information that refer to expectations, beliefs, plans, projections, objectives, performance or other characterizations of future events or circumstances, including any underlying assumptions, are forward-looking. All forward-looking statements are based upon the Company's current expectations and various assumptions. The Company believes there is a reasonable basis for its expectations and beliefs, but they are inherently uncertain. The Company may not realize its expectations, and its beliefs may not prove correct. Actual results could differ materially from those described or implied by such forward-looking statements as a result of various important factors, including, without limitation, the important factors discussed under the caption "Risk Factors" in its Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2023, as such factors may be updated from time to time in its other filings with the SEC, which are accessible on the SEC's website at www.sec.gov. These and other important factors 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 the Company may elect to update such forward-looking statements at some point in the future, except as required by law, it disclaims any obligation to do so, even if subsequent events cause our views to change. These forward-looking statements should not be relied upon as representing the Company's views as of any date subsequent to the date of this press release.

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