Atea Pharmaceuticals Reports Fourth Quarter and Full Year 2023 Financial Results and Provides Business Update

February 28, 2024

Final Results Confirm 98% Sustained Virologic Response Rate at Week 4 Post-Treatment (SVR4) from Lead-in Cohort in Phase 2 HCV Study

Enrollment in Phase 3 SUNRISE-3 Study Has Surpassed 1,400 COVID-19 Patients in Monotherapy Population; Two Interim Analyses by Independent Data Safety Monitoring Board (DSMB) Planned for 1H'24 with Topline Results Expected 2H'24

Conference Call at 4:30 pm ET Today

BOSTON, Feb. 28, 2024 (GLOBE NEWSWIRE) -- Atea Pharmaceuticals, Inc. (Nasdaq: AVIR) (Atea or 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 fourth quarter and full year ended December 31, 2023 and provided a business update.

"2023 was marked by strong operational execution, as evidenced by the rapid enrollment of our Phase 2 HCV combination study of bemnifosbuvir and ruzasvir and our ability to leverage global surges in COVID-19 to meaningfully advance our Phase 3 SUNRISE-3 study," said Jean-Pierre Sommadossi, PhD, Chief Executive Officer and Founder of Atea Pharmaceuticals.

"Our clinical progress has led to exciting data for our HCV program. I am pleased to share that the 98% SVR4 rate was confirmed in the final results from the lead-in cohort of the Phase 2 combination study. Enrollment of the remainder of this study is ongoing with topline results anticipated in the second half of 2024," continued Dr. Sommadossi. "In the US, it is estimated that there are 2.4 million individuals infected with HCV. Rates of new infections and reinfection exceed cure rates, leading to a continuing increase of prevalence. The key unmet needs identified by healthcare providers in market research recently conducted by Atea include shorter length of treatment with fewer contraindications, particularly drug-drug interactions, which we believe the combination of bemnifosbuvir and ruzasvir has the potential to address."

"Patient enrollment for SUNRISE-3 has correlated with the latest winter wave. Currently, more than 1,400 patients have been enrolled in the monotherapy population triggering our second interim analysis for safety and futility by the independent DSMB. For SUNRISE-3, we anticipate several upcoming events including the first interim analysis in March of 2024, the second interim analysis in the second quarter of 2024 and topline results during the second half of 2024," said Dr. Sommadossi. "COVID-19 continues to be a threat worldwide and there remains an urgent need for new oral antiviral treatment options to protect those who continue to be the most vulnerable to severe outcomes from infection such as the elderly, immunocompromised and those with underlying risk factors."

Hepatitis C Virus (HCV) Phase 2 Update -- New Results

Phase 2 HCV Combination Study: Atea is currently conducting a global Phase 2 clinical trial of bemnifosbuvir, an oral nucleotide polymerase inhibitor, in combination with ruzasvir, an oral NS5A inhibitor, in treatment-naïve, HCV-infected patients either without cirrhosis or with compensated cirrhosis. This study is designed to evaluate the safety and efficacy of eight weeks of treatment with the combination consisting of once-daily bemnifosbuvir 550 mg and ruzasvir 180 mg. Up to approximately 280 HCV-infected, treatment-naïve patients across all genotypes (GT), including the lead-in cohort of 60 patients without cirrhosis, are expected to be enrolled in this Phase 2 clinical trial. The primary endpoints of the study are safety and sustained virologic response (SVR) at Week 12 post-treatment (SVR12). Other virologic endpoints include virologic failure, SVR at Week 24 post-treatment (SVR24) and resistance.

Final results from the 60 patient lead-in cohort confirmed a 98% SVR4 rate across GT from 58 of 59 patients. These results, which are consistent with the initial results from this cohort announced in January 2024, include a patient with poor adherence who did not achieve SVR4 and exclude one patient who did not attend the Week 4 post-treatment follow-up. The SVR4 rate exceeded the protocol-defined efficacy criterion of ≥90% SVR4 for continuing the study.

As a result, in January 2024 patient enrollment was reinitiated for up to 220 patients in the study, including patients with cirrhosis. Final SVR12 results from all patients enrolled in the Phase 2 study are anticipated in the second half of 2024.

In the lead-in cohort, very rapid viral kinetics were observed with viral load for each patient near or below the lower limit of quantification (LLOQ) at four weeks of treatment, which is supportive of an eight-week treatment regimen for the combination of bemnifosbuvir and ruzasvir. All 60 patients in the lead-in cohort achieved viral load below the LLOQ by the end of the eight-week treatment.

The combination of bemnifosbuvir and ruzasvir in the lead-in cohort was generally safe and well-tolerated and there were no drug related serious adverse events, no treatment discontinuations and adverse events were mostly mild.

COVID-19 Phase 3 SUNRISE-3 Update

SUNRISE-3 Trial of Bemnifosbuvir in High-Risk Outpatients with COVID-19: Atea is continuing to enroll patients in the global, multicenter, randomized, double-blind, placebo-controlled, Phase 3 SUNRISE-3 trial evaluating bemnifosbuvir or placebo administered concurrently with locally available standard of care (SOC). SUNRISE-3 is 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 is comprised of 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 primary endpoint of the SUNRISE-3 study is all-cause hospitalization or death through Day 29 in the supportive care monotherapy cohort. The trial includes two interim analyses by the DSMB to assess safety and futility, conducted after approximately 650 and 1,350 evaluable patients, respectively, in the supportive care monotherapy cohort have reached Day 29 post treatment. Atea reports that more than 1,400 patients have been enrolled in this cohort. As a result, both the first and second DSMB interim analyses are now planned. The Company expects to report the outcome of each interim analysis following each meeting of the DSMB. Currently, the report relating to the outcome of the first interim analysis is expected by the end of March 2024 and the report relating to the outcome of the second interim analysis is expected in the second quarter of 2024. Topline results from the SUNRISE-3 trial are anticipated in the second half of 2024.

The SUNRISE-3 patient population includes 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 and adolescents are eligible for enrollment.

The evaluation of bemnifosbuvir for the treatment of COVID-19 has been granted Fast Track designation by the U.S. Food and Drug Administration (FDA).

COVID-19 Program for Second Generation Protease Inhibitors: As part of a multi-pronged approach against COVID-19, Atea is engaged in efforts directed to the identification of second-generation protease inhibitors. Activities to select a novel proprietary compound are underway.

Fourth Quarter and Full Year 2023 Financial Results

Cash, Cash Equivalents and Marketable Securities: $578.1 million at December 31, 2023 compared to $646.7 million at December 31, 2022.

Research and Development Expenses: Research and development expenses were $35.0 million and $114.2 million for the fourth quarter and full year 2023, respectively, compared to $27.5 million and $81.9 million for the corresponding periods in 2022. The increase was primarily driven by higher external spend related to our COVID-19 Phase 3 SUNRISE-3 clinical trial and our Phase 2 clinical trial of the combination of bemnifosbuvir and ruzasvir for the treatment of HCV.

General and Administrative Expenses: General and administrative expenses were $11.5 million and $49.9 million for the fourth quarter and full year 2023, respectively, compared to $12.4 million and $48.7 million for the corresponding periods in 2022.

Interest Income and Other, Net: Interest income and other, net was $7.8 million and $29.2 million for the fourth quarter and full year 2023, respectively, compared to $5.6 million and $11.2 million for the corresponding periods in 2022. The increase was primarily the result of investing in higher yield marketable securities and higher interest rates.

Income Taxes: Income tax expense was $0.3 million and $1.0 million for the fourth quarter and full year 2023, respectively, compared to an income tax expense of $0.1 million and income tax benefit of $3.6 million for the corresponding periods in 2022. 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.

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

	Three Months Ended December 31,		Year Ended December 31,	
	2023	2022	2023	2022
Operating expenses				
Research and development	$ 35,045	$ 27,540	$ 114,243	$ 81,936
General and administrative	11,528	12,359	49,919	48,714
Total operating expenses	46,573	39,899	164,162	130,650
Loss from operations	(46,573)	(39,899)	(164,162)	(130,650)
Interest income and other, net	7,758	5,591	29,224	11,151
Loss before income taxes	(38,815)	(34,308)	(134,938)	(119,499)
Income tax benefit (expense)	(349)	(123)	(1,018)	3,590
Net loss	$ (39,164)	$ (34,431)	$ (135,956)	$ (115,909)
Other comprehensive income (loss):				
Unrealized gain (loss) on available-for- sale investments	469	171	891	(684)
Comprehensive loss	$ (38,695)	$ (34,260)	$ (135,065)	$ (116,593)
Net loss per share – basic and diluted	$ (0.47)	$ (0.41)	$ (1.63)	$ (1.39)
Weighted-average number of common shares – basic and diluted	83,435,513	83,287,639	83,389,750	83,245,385

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

	December 31, 2023	December 31, 2022
Cash, cash equivalents and marketable securities	$ 578,106	$ 646,709
Working capital(1)	558,079	642,444
Total assets	594,968	666,708
Total liabilities	39,776	26,136
Total stockholders' equity	555,192	640,572

(1) The Company defines working capital as current assets less current liabilities. See the Company's consolidated financial statements in its Annual Report on Form 10-K for the year ended December 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 fourth quarter and full year 2023 financial results and provide a business update today at 4:30 p.m. ET. To access the live conference call, participants may register here. The live audio webcast of the call will be available under "Events and Presentations" in the Investor Relations section of the Atea Pharmaceuticals website at ir.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 archive of the audio webcast will be available on Atea Pharmaceuticals' website approximately two hours after the conference call and will remain available for at least 90 days following the event.

About Bemnifosbuvir and Ruzasvir for Hepatitis C Virus (HCV)

Bemnifosbuvir, an oral nucleotide polymerase inhibitor, 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 GT 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 eight to 12 weeks in healthy and HCV-infected subjects.

Ruzasvir, an oral NS5A inhibitor, has demonstrated highly potent and pan-genotypic antiviral activity in preclinical (picomolar range) and clinical studies. Ruzasvir 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. Ruzasvir's PK profile supports once-daily dosing.

About Bemnifosbuvir for COVID-19

Bemnifosbuvir targets the SARS-CoV-2 RNA polymerase (nsp12), a highly conserved gene which 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 nucleotidyltransferase (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, XBB and EG.5.1.

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 and updated from time to time under the caption "Risk Factors" in the reports the Company files with the SEC, including annual reports on Form10-K, quarterly reports on Form10-Q, current reports on Form 8-K and other filings each of 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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