Atea Pharmaceuticals Reports First Quarter 2024 Financial Results and Provides Business Update

May 14, 2024

Full Enrollment Achieved in Global Phase 3 SUNRISE-3 Trial for Treatment of COVID-19 with Results Expected 2H'24

Global Phase 2 HCV Study On Track to Report Complete SVR12 Results 2H'24

Multiple Presentations Showcasing Preclinical and New Phase 2 Efficacy Data to be Presented at European Association for the Study of the Liver (EASL) Congress 2024

Conference Call at 4:30 pm ET Today

BOSTON, May 14, 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 first quarter ended March 31, 2024 and provided a business update.

"Our strong operational execution, in combination with the surge of COVID-19 infections related to the JN.1 variant, led to the completion of enrollment of high-risk patients in the global Phase 3 SUNRISE-3 study ahead of our guidance. This significant achievement brings us one step closer to potentially delivering bemnifosbuvir as a new oral antiviral treatment option for COVID-19," said Jean-Pierre Sommadossi, PhD, Chief Executive Officer and Founder of Atea. "COVID-19 continues to be a threat, leaving the most vulnerable, including the elderly, immunocompromised, undervaccinated, and those with underlying risk factors at risk for disease progression. We look forward to reporting the results from SUNRISE-3 during the second half of 2024."

"In addition to our substantial progress in COVID-19, we are quickly advancing enrollment in our global Phase 2 study evaluating the combination of bemnifosbuvir and ruzasvir in treatment-naïve, HCV-infected patients, including patients with compensated cirrhosis. Despite currently available HCV treatment options, infection and reinfection rates annually exceed cure rates in the U.S. where over 2 million individuals are estimated to be infected," continued Dr. Sommadossi. "We are very excited about the upcoming presentations at EASL, which include preclinical and new Phase 2 efficacy data from the lead-in cohort, and we look forward to reporting the full results from our Phase 2 study during the second half of 2024."

COVID-19 Phase 3 SUNRISE-3 Trial Update

SUNRISE-3 Trial of Bemnifosbuvir in High-Risk Outpatients with COVID-19: Atea has completed enrollment 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 exclusively enrolled high-risk outpatients with mild or moderate COVID-19. Patients were randomized 1:1 to receive bemnifosbuvir 550 mg twice-daily (BID) or placebo BID for five days.

The primary endpoint of the SUNRISE-3 trial is all-cause hospitalization or death through Day 29 in the supportive care monotherapy cohort. In addition, secondary endpoints will measure patient outcomes in the trial through Day 60 post-treatment.

The trial is comprised of two study populations based on the type of SOC administered at the investigator's discretion: 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). In this study, 2,221 patients were randomized into the supportive care monotherapy cohort and only 74 patients were randomized into the combination cohort, with 77% enrolled in the US. The clear preference by investigators to enroll patients in the monotherapy cohort highlights the continuing unmet medical need for new oral COVID-19 treatment options for high-risk patients.

The SUNRISE-3 high risk patient population consists of 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.

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 with a differentiated profile are underway.

Hepatitis C Virus (HCV) Phase 2 Update

Phase 2 HCV Combination Study: Atea is currently conducting a global Phase 2 clinical trial of bemnifosbuvir, an oral nucleotide NS5B 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, 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 all genotypes 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 additional patients, including patients with cirrhosis. Topline 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.

Favorable Bemnifosbuvir Data Presented at the European Society of Clinical Microbiology & Infectious Diseases (ESCMID) Global 2024

In April 2024, Atea presented Phase 1 data showing that bemnifosbuvir does not alter cardiac repolarization. Results from the study showed that the studied doses (up to 1,100 mg twice daily) did not have any clinically relevant effect on cardiac repolarization, heart rate, PR interval (time between atrial depolarization and ventricular depolarization), or QRS (ventricular depolarization) duration. The results also demonstrated that a QTc effect (the duration of the QT interval adjusted for the participant's heart rate) greater than 10 milliseconds (established threshold of regulatory concern) is unlikely across the full observed plasma concentration ranges of bemnifosbuvir and its metabolites.

These clinical data confirm preclinical *in vitro* and *in vivo* study results, suggesting bemnifosbuvir has a low potential for cardiotoxicity with no predicted arrhythmic QTc-interval prolongation or inhibition of the human mitochondrial DNA-directed RNA polymerase.

First Quarter 2024 Financial Results

Cash, Cash Equivalents and Marketable Securities: $541.5 million at March 31, 2024 compared to $578.1 million at December 31, 2023.

Research and Development Expenses: Research and development expenses increased by $28.6 million from $29.0 million for the three months ended March 31, 2023 to $57.6 million for the three months ended March 31, 2024. 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. This increase was partially offset by a reduction of $1.0 million in internal costs primarily due to a decrease in consulting and other research and development expenses.

General and Administrative Expenses: General and administrative expenses decreased by $0.4 million from $12.6 million for the three months ended March 31, 2023 to $12.2 million for the three months ended March 31, 2024. The net decrease was primarily related to lower professional fees.

Interest Income and Other, Net: Interest income and other, net, increased by $0.6 million for the three months ended March 31, 2024 compared to the three months ended March 31, 2023, primarily due to investing in higher yield marketable securities and higher interest rates.

Income Taxes: Income tax expense of $0.2 million remained unchanged for each of the three months ended March 31, 2024 and March 31, 2023.

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

	Three Months Ended March 31,	
	2024	**2023**
Operating expenses:		
Research and development	$ 57,575	$ 28,954
General and administrative	12,231	12,615
Total operating expenses	69,806	41,569
Loss from operations	(69,806)	(41,569)
Interest income and other, net	6,868	6,299
Loss before income taxes	(62,938)	(35,270)
Income tax expense	(231)	(197)
Net loss	$ (63,169)	$ (35,467)
Other comprehensive loss:		
Unrealized gain (loss) on available-for-sale investments	(388)	377
Comprehensive loss	$ (63,557)	$ (35,090)
Net loss per share – basic and diluted	$ (0.75)	$ (0.43)
Weighted-average common shares – basic and diluted	83,916,193	83,332,397

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

	March 31, 2024	December 31, 2023
Cash, cash equivalents, and marketable securities	$ 541,491	$ 578,106
Working capital[(1)]	507,453	558,079
Total assets	553,029	594,968
Total liabilities	48,658	39,776
Total stockholders' equity	504,371	555,192

(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, 2024 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 2024 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 for COVID-19

Bemnifosbuvir, an oral nucleotide polymerase inhibitor, 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 nucleotityltransferase (NiRAN) inhibition, which have 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, EG.5.1 and JN.1.

About Bemnifosbuvir and Ruzasvir for Hepatitis C Virus (HCV)

Bemnifosbuvir has been shown in *in vitro* studies to be approximately 10-fold more active than sofosbuvir (SOF) against a panel of laboratory strains and clinical isolates of HCV GT 1–5. *In vitro* studies have also 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. Across both HCV and COVID-19 programs, bemnifosbuvir has been administered to over 2,100 subjects and has been well-tolerated at doses up to 550 mg for durations up to 12 weeks in healthy subjects and patients.

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 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 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 conference call and audio webcast and the anticipated time of release of clinical trial results from the Company's COVID-19 and HCV programs. 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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