Atea Pharmaceuticals Reports Fourth Quarter and Full Year 2024 Financial Results and Provides Business Update

March 6, 2025

Successful End-of-Phase 2 Meeting with FDA and Alignment on Phase 3 Program for Hepatitis C Virus (HCV)

Patient Enrollment in Global Phase 3 HCV Program Expected to Start in April 2025

Conference Call at 4:30 pm ET Today

BOSTON, March 06, 2025 (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, 2024 and provided a business update.

“I am pleased to share that we recently had a successful End-of-Phase 2 meeting with the FDA, and we expect enrollment to begin next month in our global HCV Phase 3 program evaluating the regimen of bemnifosbuvir and ruzasvir. Results to-date demonstrate the potency of our potential best-in-class regimen with a short 8-week treatment duration, low risk of drug-drug interactions and convenience with no food effect,” said Jean-Pierre Sommadossi, PhD, Chief Executive Officer and founder of Atea. “Globally, the burden of untreated HCV infection is significant, with approximately 50 million people living with the disease, including up to 4 million in the US. We believe our regimen, if approved, has the potential to play a major role in the eradication of HCV in the US and to disrupt and expand the global HCV market, which is approximately $3 billion in annual net sales.”

“In addition to the substantial clinical progress, business updates include recent steps we have taken to further enhance shareholder value. This includes the retention of an investment bank to assist us in the exploration of strategic partnerships related to our Phase 3 HCV program, cost-cutting actions to increase efficiency in the management of infrastructure expenditures and the appointment of a new independent director, Arthur S. Kirsch, who brings decades of financial and strategic advisory experience to our Board of Directors,” continued Dr. Sommadossi.

Global Phase 3 Program for HCV

Based upon a successful engagement with the US Food and Drug Administration (FDA) at the End-of-Phase 2 meeting in January 2025, Atea is initiating the global Phase 3 program and expects patient enrollment to start in April 2025.

In December 2024, Atea announced that its Phase 2 study evaluating the regimen of bemnifosbuvir, a nucleotide analog polymerase inhibitor, and ruzasvir, an NS5A inhibitor, for treatment of hepatitis C virus (HCV), met its primary endpoints. Atea plans to conduct two open label Phase 3 trials, one in the US and Canada and one outside of North America. Each Phase 3 trial is expected to enroll approximately 800 treatment-naïve patients, including those with and without compensated cirrhosis. For patients without cirrhosis, 8 weeks of the regimen of bemnifosbuvir and ruzasvir will be compared to 12 weeks of the regimen of sofosbuvir and velpatasvir. For patients with compensated cirrhosis, 12 weeks of the regimen of bemnifosbuvir and ruzasvir will be compared to 12 weeks of the regimen of sofosbuvir and velpatasvir. In the US, it is estimated that more than 90% of people with HCV are non-cirrhotic.

The primary endpoint for both trials encompasses sustained virologic response 12 weeks post-treatment (SVR12) in each arm and is HCV RNA < lower limit of quantitation (LLOQ) 24 weeks from the start of treatment. Measurement at 24 weeks from the start of treatment is selected to ensure the primary endpoint occurs at the same relative timepoint from start of treatment in all patients.

Since it is not feasible to blind the clinical trial sites and patients to the treatment assignment due to the varying treatment lengths and packaging of the commercial active comparator, the Phase 3 clinical trials will be run as open-label studies. However, throughout the study, Atea personnel will remain blinded to the individual patient treatment assignment.

Phase 2 Study Results for HCV

Atea made significant progress advancing its HCV program in 2024. The global Phase 2 study evaluating the regimen of bemnifosbuvir and ruzasvir for the treatment of HCV met its primary endpoints of safety and SVR12. Primary endpoint results demonstrated a 98% (208/213) SVR12 rate in the per-protocol treatment adherent patient population after eight weeks of treatment with the regimen of bemnifosbuvir and ruzasvir. The efficacy evaluable patient population, which included 17% treatment non-adherent patients, achieved a 95% (242/256) SVR12 rate, demonstrating the robust potency and forgiveness of the regimen. The regimen was generally safe and well-tolerated with no drug-related serious adverse events or treatment discontinuations. Full data from the Phase 2 study are anticipated to be presented at a scientific meeting during the first half of 2025.

The global Phase 2 study enrolled 275 treatment-naïve patients, both with and without compensated cirrhosis. The study was designed to evaluate the safety and efficacy of eight weeks of treatment with the regimen consisting of once-daily bemnifosbuvir 550 mg and ruzasvir 180 mg.

The primary endpoints of the study were safety and SVR12 in the per-protocol treatment adherent population. Secondary and other endpoints included SVR12 in the per-protocol population regardless of treatment adherence (efficacy evaluable), virologic failure and resistance.

Business Update

In December 2024, Atea announced that it had engaged Evercore, an independent global investment bank, to assist the Company in the exploration of

strategic partnerships related to its Phase 3 program for the treatment of HCV.

During the first quarter of 2025, Atea reduced its workforce by approximately 25%. The action is intended to enhance efficiency in the management of infrastructure expenditures and is expected to result in cost savings of approximately $15 million through 2027.

In February 2025, Atea appointed Arthur S. Kirsch to the Company's Board of Directors. Mr. Kirsch has decades of experience in investment banking and capital markets, has advised on a wide range of strategic transactions and has extensive knowledge of the healthcare and life sciences industries.

Fourth Quarter & Full Year 2024 Financial Results

Cash, Cash Equivalents and Marketable Securities: $454.7 million at December 31, 2024 compared to $578.1 million at December 31, 2023.

Research and Development Expenses: Research and development expenses were $25.7 million and $144.1 million for the fourth quarter and full year 2024, respectively, compared to $35.0 million and $114.2 million for the corresponding periods in 2023. The increase in expenses for the full year was primarily driven by higher external spend related to Atea's COVID-19 Phase 3 SUNRISE-3 clinical trial and the Phase 2 clinical trial of the regimen of bemnifosbuvir and ruzasvir for the treatment of HCV.

General and Administrative Expenses: General and administrative expenses were $13.3 million and $48.9 million for the fourth quarter and full year 2024, respectively, compared to $11.5 million and $49.9 million for the corresponding periods in 2023.

Interest Income and Other, Net: Interest income and other, net was $5.7 million and $25.5 million for the fourth quarter and full year 2024, respectively, compared to $7.8 million and $29.2 million for the corresponding periods in 2023. The decrease was primarily the result of lower invested balances during 2024.

Income Taxes: Income tax expense was $0.2 million and $0.9 million for the fourth quarter and full year 2024, respectively, compared to income tax expense of $0.3 million and income tax expense of $1.0 million for the corresponding periods in 2023.

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,	
	2024	2023	2024	2023
Operating expenses				
Research and development	$ 25,671	$ 35,045	$ 144,101	$ 114,243
General and administrative	13,355	11,528	48,849	49,919
Total operating expenses	39,026	46,573	192,950	164,162
Loss from operations	(39,026)	(46,573)	(192,950)	(164,162)
Interest income and other, net	5,708	7,758	25,490	29,224
Loss before income taxes	(33,318)	(38,815)	(167,460)	(134,938)
Income tax expense	(225)	(349)	(925)	(1,018)
Net loss	$ (33,543)	$ (39,164)	$ (168,385)	$ (135,956)
Other comprehensive loss				
Unrealized gain (loss) on available-for-sale investments	(408)	469	26	891
Comprehensive loss	$ (33,951)	$ (38,695)	$ (168,359)	$ (135,065)
Net loss per share - basic and diluted	$ (0.40)	$ (0.47)	$ (2.00)	$ (1.63)
Weighted-average number of common shares - basic and diluted	84,463,059	83,435,513	84,264,715	83,389,750

Selected Condensed Consolidated Balance Sheet Data

(in thousands)

(unaudited)

	December 31, 2024	December 31, 2023
Cash, cash equivalents and marketable securities	$ 454,721	$ 578,106
Working capital[(1)]	443,752	558,079
Total assets	464,668	594,968
Total liabilities	25,801	39,776
Total stockholder's equity	438,867	555,192

(1) Atea 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, 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 fourth quarter and full year 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 as well as presentation materials 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 HCV

HCV is a blood-borne, positive-sense, single-stranded (ss) RNA virus that primarily infects liver cells. HCV is a leading cause of chronic liver disease and liver transplants, spreading via blood transfusion, hemodialysis and needle sticks, with 242,000 deaths occurring each year. Despite the availability of direct-acting antivirals, HCV continues to be a significant global healthcare issue. An estimated 50 million people worldwide are chronically infected with HCV and there are approximately one million new infections each year. In the US, between 2.4 and 4 million people are estimated to have HCV with annual new infections outpacing treatment rates. HCV infections in the US predominate in patients in the age group between 20-49 years old, and it is estimated that less than 10% of the HCV infected patients in the US have cirrhosis. Chronic HCV infection is the leading cause of liver cancer in the US, Europe and Japan.

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 substitutions (S282T), with up to 58-fold more potency than SOF. The PK profile of bemnifosbuvir supports once-daily dosing for the treatment of HCV. Bemnifosbuvir has been shown to have a low risk for drug-drug interactions. Bemnifosbuvir has been administered to over 2,300 subjects and has been well-tolerated at doses up to 550 mg for durations up to 12 weeks in healthy subjects and patients.

Ruzasvir has demonstrated highly potent and pan-genotypic antiviral activity in preclinical (picomolar range) and clinical studies. Ruzasvir has been administered to over 2,100 subjects at daily doses of up to 180 mg for 12 weeks and has demonstrated a favorable safety profile. The PK profile of ruzasvir 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 Atea'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. Our lead program and current focus is on the development of the regimen of bemnifosbuvir, a nucleotide analog polymerase inhibitor and ruzasvir, an NS5A inhibitor, to treat hepatitis C virus. 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 statements regarding future results of operations and financial position, including our anticipated cash runway; business strategy; current and prospective product candidates; anticipated milestone events; potential benefits of our product candidates and market opportunity; clinical trials, including, without limitation, anticipated initiation, enrollment, regulatory submission and data readout timelines; preclinical activities; product approvals; manufacturing availability; degree of market acceptance of any products that may be approved; research and development costs; and prospective collaborations and strategic partnerships. When used herein, words including "expected," "should," "anticipated," "believe." "will," "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 Atea's current expectations and various assumptions. Atea believes there is a reasonable basis for its expectations and beliefs, but they are inherently uncertain. Atea 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, uncertainties inherent in the drug discovery and development process and the regulatory submission or approval process, unexpected or unfavorable safety or efficacy data or results observed during clinical trials or in data readouts; delays in or disruptions to clinical trials or our business; our reliance on third parties over which we may not always have full control, our ability to manufacture sufficient commercial product, competition from approved treatments for HCV, as well as the other important factors discussed under the caption "Risk Factors" in Atea's Quarterly Report on Form 10-Q for the quarter ended September 30, 2024 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 Atea 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 Atea's views as of any date subsequent to the date of this press release.

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