Atea Pharmaceuticals Reports First Quarter 2025 Financial Results and Provides Business Update

May 12, 2025

Enrollment Ongoing in Phase 3 C-BEYOND Trial for Treatment of HCV

Full Phase 2 Results for Regimen of Bemnifosbuvir and Ruzasvir for HCV and Results from Three Additional Phase 1 Studies Supporting Potential Best-in-Class Profile Presented at European Association for the Study of the Liver (EASL) Congress 2025

Virtual Investor Event with Key Opinion Leader Insights on HCV to be Held May 14, 2025, at 10:00 AM ET

BOSTON, May 12, 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 first quarter ended March 31, 2025 and provided a business update.

The Company's combination regimen of bemnifosbuvir (BEM), a nucleotide analog polymerase inhibitor, and ruzasvir (RZR), an NS5A inhibitor, is in Phase 3 development for the treatment of hepatitis C virus (HCV).

"Atea has made very significant progress thus far in 2025, initiating and continuing to enroll patients in C-BEYOND, our Phase 3 clinical trial evaluating the regimen of bemnifosbuvir and ruzasvir for the treatment of HCV in the US and Canada," said Jean-Pierre Sommadossi, PhD, Chief Executive Officer and Founder of Atea. "We are also focused on initiating our second Phase 3 trial, C-FORWARD, which will be conducted at clinical sites outside of North America. We expect enrollment of patients in C-FORWARD to begin mid-year."

"We are very encouraged by the positive results of the Phase 2 clinical study and additional data presented at EASL 2025 supporting the efficacy, safety and potential best-in-class profile of our regimen of bemnifosbuvir and ruzasvir, including short treatment duration, low risk for drug-drug interactions, and convenience with no food effect," continued Dr. Sommadossi. "We believe our regimen, if approved, has the potential to increase the number of treated and cured HCV patients and to disrupt the global HCV market of approximately $3 billion in net sales."

HCV KOL Investor Event to be Held May 14, 2025 at 10:00 AM ET

Atea will host a virtual key opinion leader (KOL) investor event with a panel of HCV experts and prescribers on Wednesday, May 14, 2025, at 10:00 AM ET. To register, click here.

This KOL event will replace Atea's first quarter 2025 earnings conference call, and Quarterly calls will resume with the second quarter 2025 financial results.

This investor event will include an expert panel of several leaders in hepatology, gastroenterology, infectious diseases, and HCV treatments in the US, Canada and Europe. These experts and prescribers will discuss the current challenges experienced by people living with HCV, the full results of Atea's global Phase 2 study evaluating the regimen of BEM/RZR for the treatment of HCV, and what a new optimized HCV therapy could provide for prescribers and patients. Company management will discuss the HCV commercial market opportunity and the ongoing global Phase 3 clinical development.

Summary of Results Presented at EASL

Poster Title: Efficacy and Safety of Bemnifosbuvir and Ruzasvir after 8 Weeks of Treatment in Patients with Chronic Hepatitis C Virus (HCV) Infection (TOP-251)
Conclusion: The Phase 2 study results demonstrated that an 8-week combination regimen of BEM (550 mg) and RZR (180 mg) achieved SVR12 in 98% of treatment-adherent patients and 95% of patients regardless of treatment adherence. The regimen was safe and well-tolerated with low rates of virologic failure and no study-drug-related serious adverse events or treatment discontinuations. Treatment emergent adverse events (TEAEs) were reported in 43% (118/275) of patients. Most TEAEs were mild to moderate in intensity, with headache (9%) and nausea (8%) being the most reported. These results reinforce the potential of the combination regimen of BEM and RZR as a best-in-class treatment for HCV.

Poster Title: Pharmacokinetics of Bemnifosbuvir in Participants with Hepatic Impairment (WED-278)
Conclusion: A Phase 1 pharmacokinetic study evaluating a single 550 mg dose of BEM in participants with varying degrees of hepatic impairment showed increased drug exposure in individuals with moderate to severe liver dysfunction. However, these changes did not meaningfully affect levels of AT-273, the plasma marker for the active intracellular antiviral metabolite of BEM. No safety concerns were identified. These results support the use of BEM without dose adjustment in patients with hepatic impairment.

Poster Title: No DDI Between Bemnifosbuvir/Ruzasvir and Bictegravir/Emtricitabine/Tenofovir Alafenamide (WED-279)
Conclusion: Findings from a Phase 1 drug-drug interaction study in healthy participants demonstrated that co-administration of BEM/RZR with the standard human immunodeficiency virus (HIV) regimen bictegravir/emtricitabine/tenofovir alafenamide (B/FTC/TAF) resulted in no clinically significant pharmacokinetic changes. The co-administered HCV/HIV combinations were generally safe and well tolerated. These results support the future inclusion of HCV/HIV co-infected patients receiving these HIV therapies in the Phase 3 clinical development program for BEM/RZR.

It is estimated that in the US as many as 6 to 30% of HCV patients are co-infected with HIV.[1]

Poster Title: Pharmacokinetics of Bemnifosbuvir in Participants with Renal Impairment (WED-280)
Conclusion: A Phase 1 renal impairment study showed that a single 550 mg dose of BEM was safe and well-tolerated across participants with normal kidney function, moderate-to-severe renal impairment, and those with end-stage renal disease on hemodialysis. While the circulating inactive nucleoside metabolites of BEM increased as expected in renally impaired individuals, exposure of BEM remained consistent. These findings suggest that BEM may be used without dose adjustment in patients with renal dysfunction, including those undergoing dialysis.

About the Bemnifosbuvir / Ruzasvir HCV Phase 3 Program

Atea's HCV Phase 3 program includes two open-label Phase 3 trials, C-BEYOND in the US and Canada, and C-FORWARD, a global trial outside of North America. Each Phase 3 trial will enroll approximately 880 treatment-naïve patients, including those with and without compensated cirrhosis. The trials will compare the fixed-dose combination (FDC) regimen of BEM/RZR to the FDC regimen of sofosbuvir and velpatasvir. The regimen of BEM/RZR will be administered orally once-daily for eight weeks (in patients without cirrhosis) or 12 weeks (in patients with compensated cirrhosis) while the regimen of sofosbuvir and velpatasvir will be administered orally once-daily for 12 weeks to all patients, with or without compensated cirrhosis.

The primary endpoint for each trial is HCV RNA < lower limit of quantitation (LLOQ) at 24 weeks from the start of treatment and encompasses sustained virologic response 12 weeks post-treatment (SVR12) in each arm. Measurement at 24 weeks from the start of treatment is to ensure the primary endpoint occurs at the same relative timepoint from the start of treatment in all patients. Patient enrollment in the C-BEYOND trial is ongoing and enrollment in the C-FORWARD trial is expected to begin in mid-2025.

The initiation of the Phase 3 program follows a successful engagement with the US Food and Drug Administration (FDA) at an End-of-Phase 2 meeting in January 2025, shortly after the Company announced the topline results from the Phase 2 study evaluating the potential best-in-class regimen of BEM/RZR, including data demonstrating that the regimen met its primary endpoints of efficacy (SVR12) and safety.

Business and Organizational Updates

- In December 2024, Atea engaged Evercore, a global independent investment bank, to identify potential opportunities to enhance shareholder value. The process includes a review of a broad range of strategic alternatives, including strategic partnerships, acquisition, merger, or other business combination, sale of assets or other strategic transactions. The process is ongoing, and the Company continues to evaluate all options to maximize shareholder value.
- In the first quarter 2025, to enhance efficiency in the management of infrastructure expenditures, Atea reduced its workforce by approximately 25%. This workforce reduction is expected to result in cost savings of approximately $15 million through 2027.
- In February 2025, Arthur S. Kirsch was appointed to the Company's Board of Directors. Mr. Kirsch has extensive knowledge of the healthcare and life sciences industries gained from decades of investment banking and capital markets experience as well as extensive public board and strategic experience.
- In April 2025, Atea further refreshed its Board of Directors with the appointment of Howard H. Berman, PhD. The appointment of Dr. Berman, who is currently serving as an observer, will become effective upon the completion of Atea's 2025 Annual Meeting of Stockholders. Dr. Berman has over 20 years of entrepreneurial and life science industry experience working at the interplay of science and business.
- In April 2025, Atea announced that its Board had authorized the repurchase of up to $25 million of the Company's common stock. This authorization reflects the Company's commitment to return capital to shareholders, while maintaining the capacity to complete its global Phase 3 HCV program and position Atea for long-term success.

First Quarter 2025 Financial Results

Cash, Cash Equivalents and Marketable Securities: $425.4 million at March 31, 2025, compared to $454.7 million at December 31, 2024.

Research and Development Expenses: Research and development expenses decreased by $28.0 million from $57.6 million for the three months ended March 31, 2024, to $29.6 million for the three months ended March 31, 2025. The net decrease was primarily driven by lower external spend as Atea's COVID-19 Phase 3 SUNRISE-3 clinical trial was completed in 2024. The decrease was offset by an increase in external spend principally related to startup activities for the Company's HCV Phase 3 clinical development. Additionally, a decrease in internal research and development expenses was primarily related to lower stock-based compensation expense in the three-month period ended March 31, 2025.

General and Administrative Expenses: General and administrative expenses decreased by $2.8 million from $12.2 million for the three months ended March 31, 2024, to $9.5 million for the three months ended March 31, 2025. The net decrease was primarily related to lower stock-based compensation expense, partially offset by increased professional fees.

Interest Income and Other, Net: Interest income and other, net, decreased by $1.9 million for the three months ended March 31, 2025, compared to the three months ended March 31, 2024, primarily due to lower investment balances.

Income Taxes: Income tax expense was $0.2 million for the three months ended March 31, 2025, and March 31, 2024.

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

	Three Months Ended March 31,	
	2025	2024
Operating expenses		
Research and development	$ 29,584	$ 57,575
General and administrative	9,457	12,231
Total operating expenses	39,041	69,806
Loss from operations	(39,041)	(69,806)
Interest income and other, net	4,972	6,868
Loss before income taxes	(34,069)	(62,938)
Income tax expense	(203)	(231)
Net loss	$ (34,272)	$ (63,169)
Other comprehensive loss		
Unrealized loss on available-for-sale investments	(115)	(388)
Comprehensive loss	$ (34,387)	$ (63,557)
Net loss per share - basic and diluted	$ (0.40)	$ (0.75)
Weighted-average number of common shares - basic and diluted	85,159,254	83,916,193

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

	March 31, 2025	December 31, 2024
Cash, cash equivalents and marketable securities	$ 425,436	$ 454,721
Working capital[(1)]	411,961	443,752
Total assets	439,964	464,668
Total liabilities	28,880	25,801
Total stockholder's equity	411,084	438,867

(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, 2025, for further detail regarding its current assets and liabilities.

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 approximately 240,000 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 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 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. Atea's lead program and current focus is on the development of the combination of bemnifosbuvir, a nucleotide analog polymerase inhibitor, and ruzasvir, an NS5A inhibitor, to treat 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 statements regarding the potential best-in-class profile of the regimen of BEM and RZR for the treatment of HCV, the potential opportunity created by the regimen to increase the number of patients treated and cured, the opportunity to disrupt the global HCV market, the expected time of commencement of enrollment in the C-FORWARD Phase 3 clinical trial, future results of operations and financial position, business strategy, anticipated milestone events and timelines for clinical trials, benefits of cost savings initiatives, repurchases under the Company's share repurchase program, the timing and outcome of the Company's strategic alternatives review, the timing and agenda of the Company's KOL event and the Company's plans to resume Quarterly earnings calls in the second quarter of 2025. 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, the timeline for the completion of the strategic alternatives review process is unknown and there can be no assurance that the process will result in any particular outcome; dependence on the success of Atea’s most advanced product candidates, in particular the combination of BEM and RZR for the treatment of 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 March 31, 2025 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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[1] https://clinicalinfo.hiv.gov/en/guidelines/hiv-clinical-guidelines-adult-and-adolescent-opportunistic-infections/hepatitis-c-virus#:~:text=Estimates%20of%20HCV%20coinfection%20in,of%20HIV%20transmission%20risk%20factors.&text=In%20the%20United%20States%2C%20it,HIV%20also%20have%20HCV%20infection