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

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Full Enrollment Achieved in Global Phase 2 Hepatitis C Virus (HCV) Study; Complete SVR12 Results Expected 4Q'24

Bemnifosbuvir and Ruzasvir HCV Data Presented at EASL: Support Best-in-Class Potential with High Antiviral Potency, Low Risk of Drug Interaction, Short Treatment Duration and High Barrier to Resistance

Results from COVID-19 Global Phase 3 SUNRISE-3 Trial Expected 2H'24

Conference Call at 4:30 pm ET Today

BOSTON, Aug. 07, 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 second quarter ended June 30, 2024, and provided a business update.

"The first half of 2024 was marked by strong operational execution and significant clinical progress. We completed patient enrollment in both the global Phase 3 SUNRISE-3 study of bemnifosbuvir for the treatment of COVID-19 and the global Phase 2 study evaluating the combination of bemnifosbuvir and ruzasvir in treatment-naïve, HCV-infected patients," said Jean-Pierre Sommadossi, PhD, Chief Executive Officer and Founder of Atea. "Delivering treatment options to address the unmet needs for both COVID-19 and HCV patients remains of critical importance and we look forward to reporting results from both studies this year."

"Today, in the US, the reported annual incidence of approximately 100,000 new chronic HCV infections is outpacing the number of people cured with direct-acting antivirals. Many HCV patients take concomitant medications and in the wake of the opioid epidemic, people with substance abuse disorders and other populations with mental health disorders associated with poor medication adherence, are at the highest risk for HCV. New differentiated HCV therapies that offer low risk of drug-drug interactions combined with short treatment duration are required to address these needs," continued Dr. Sommadossi. "The bemnifosbuvir and ruzasvir data we recently presented at the EASL Congress demonstrate a potential best-in-class profile and the promise of this combination to address the unmet needs of today's HCV patient."

COVID-19 Phase 3 SUNRISE-3 Trial Update

SUNRISE-3 Trial of Bemnifosbuvir in High-Risk Outpatients with COVID-19: The global, multicenter, randomized, double-blind, placebo-controlled, Phase 3 SUNRISE-3 trial is evaluating bemnifosbuvir or placebo administered concurrently with the 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. Topline results from the study are expected in the second half of 2024.

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% of all trial patients 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.

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: In June 2024, Atea completed patient enrollment in the 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 enrolled 275 patients, including the lead-in cohort of 60 patients without cirrhosis. The 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.

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. SVR12 results from all patients in the Phase 2 trial are expected

during the fourth quarter of 2024.

Positive Data for Bemnifosbuvir and Ruzasvir for Treatment of HCV Presented at European Association of the Study of Liver (EASL) Congress 2024: In June 2024, Atea presented at EASL new clinical data from the lead-in cohort (n=60) of the ongoing Phase 2 study of the combination of bemnifosbuvir and ruzasvir for the treatment of HCV. With an 8-week treatment duration, data from the lead-in cohort of non-cirrhotic patients showed a 97% SVR12 rate, which is the primary efficacy endpoint of the study. Among the 60 patients in the lead-in cohort, two subjects (GT1b and GT2b) experienced post-treatment relapse or failure. Each of these patients had low plasma drug levels and similar viral mutations at both the baseline and 12-weeks post-treatment timepoint, which indicate that the relapse or failure was due to treatment non-adherence rather than viral failure due to resistance. These results also showed a 100% SVR12 rate in participants infected with genotype 3 (n=13), a historically difficult-to-treat genotype of HCV. The combination regimen was well tolerated, with no drug-related serious adverse events or treatment discontinuations. In addition to the clinical trial results at EASL, Atea also presented preclinical data further demonstrating a high barrier to resistance and favorable pharmacokinetics for bemnifosbuvir and a low risk of drug-drug interactions for ruzasvir. Atea has previously reported a low risk of drug-drug interactions for bemnifosbuvir.

Selected Fixed Dose Combination Tablet for Phase 3 Program: Atea recently selected the fixed dose combination (FDC) tablet for the Phase 3 program and subsequent commercialization. The selected FDC tablet achieved drug exposure comparable to individually administered bemnifosbuvir and ruzasvir used in Phase 2 and other studies. The selected FDC tablet will decrease the daily pill count from four tablets to two tablets, which is more convenient for patients. In addition, there was no food effect with the FDC tablet in a recent study that showed a high fat, high calorie meal did not affect the exposure of either bemnifosbuvir or ruzasvir.

Second Quarter 2024 Financial Results

Cash, Cash Equivalents and Marketable Securities: $502.2 million at June 30, 2024 compared to $578.1 million at December 31, 2023.

Research and Development Expenses: Research and development expenses increased by $12.6 million from $22.1 million for the three months ended June 30, 2023 to $34.7 million for the three months ended June 30, 2024. The increase was primarily driven by higher external spend related to the advancement of both 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 approximately $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 $1.0 million from $13.2 million for the three months ended June 30, 2023 to $12.2 million for the three months ended June 30, 2024. The net decrease was primarily related to lower professional fees.

Interest Income and Other, Net: Interest income and other, net, decreased by $0.7 million for the three months ended June 30, 2024 compared to the three months ended June 30, 2023, primarily due to lower investment balances.

Income Taxes: Income tax expense of $0.2 million remained unchanged for each of the three months ended June 30, 2024 and June 30, 2023.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	**2023**	**2024**	**2023**
Operating expenses				
Research and development	$ 34,696	$ 22,063	$ 92,271	$ 51,017
General and administrative	12,220	13,172	24,451	25,787
Total operating expenses	46,916	35,235	116,722	76,804
Loss from operations	(46,916)	(35,235)	(116,722)	(76,804)
Interest income and other, net	6,637	7,303	13,505	13,602
Loss before income taxes	(40,279)	(27,932)	(103,217)	(63,202)
Income tax expense	(243)	(251)	(474)	(448)
Net loss	$ (40,522)	$ (28,183)	$ (103,691)	$ (63,650)
Other comprehensive loss				
Unrealized gain (loss) on available-for-sale investments	(99)	(3)	(487)	374
Comprehensive loss	$ (40,621)	$ (28,186)	$ (104,178)	$ (63,276)
Net loss per share - basic and diluted	$ (0.48)	$ (0.34)	$ (1.23)	$ (0.76)
Weighted-average number of common shares - basic and diluted	84,253,700	83,399,377	84,069,646	83,361,398

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

	June 30, 2024	December 31, 2023

Cash, cash equivalents and marketable securities	$ 502,214	$ 578,106
Working capital[(1)]	479,750	558,079
Total assets	510,384	594,968
Total liabilities	33,914	39,776
Total stockholder's equity	476,470	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 June 30, 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 second 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 the recent subvariants BA.5, XBB, EG.5.1 and JN.1.

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

About Bemnifosbuvir and Ruzasvir for Hepatitis C Virus (HCV)

Bemnifosbuvir, an oral HCV NS5B inhibitor, 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 2,200 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 HCV NS5A inhibitor, has demonstrated highly potent and pan-genotypic antiviral activity in preclinical (picomolar range) and clinical studies. Ruzasvir has been administered to over 1,500 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 Form 10-K, quarterly reports on Form 10-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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