Atea Pharmaceuticals Reports Fourth Quarter and Full Year 2021 Financial Results and Provides Business Update

February 28, 2022

Developing bemnifosbuvir (AT-527), a nucleotide analog, as preferred backbone of combination therapy for COVID-19, progressing to Phase 2 combination clinical trial in 2H 2022

Initiating Phase 2 combination clinical trial of bemnifosbuvir and ruzasvir (RZR) as potential best-in-class pan genotypic regimen for hepatitis C virus (HCV) in 2H 2022

Advancing AT-752 as a potential first antiviral treatment for dengue fever in Phase 2 program in 1H 2022

Conference call at 4:30 p.m. ET today

BOSTON, Feb. 28, 2022 (GLOBE NEWSWIRE) -- Atea Pharmaceuticals, Inc. (Nasdaq: AVIR) ("Atea"), a clinical-stage biopharmaceutical company, today reported financial results for the fourth quarter and full year ended December 31, 2021 and provided a business update.

"During 2022, we expect to make meaningful progress advancing three Phase 2 programs in COVID-19, HCV and dengue fever," said Jean-Pierre Sommadossi, PhD, Chief Executive Officer and Founder of Atea Pharmaceuticals. "For COVID-19, our priority is to develop a combination regimen with bemnifosbuvir and a protease inhibitor. We believe that combination therapies will be needed to treat broader patient populations, as new COVID-19 variants occur, and viral drug resistance will likely emerge to protease inhibitor monotherapy. Nucleos(t)ide analogs target a highly conserved enzyme responsible for viral replication and have a higher barrier to resistance than drugs in other antiviral classes."

"The recent in-licensing of RZR expands our pipeline and accelerates the timeline of our HCV program with a Phase 2-ready NS5A inhibitor. We believe that the combination of RZR and bemnifosbuvir has the potential to be a best-in-class pan-genotypic combination regimen to help fight the increase in HCV infections caused by the opioid crisis, IV drug use and HCV reinfection," continued Dr. Sommadossi. "Additionally, we are making significant progress advancing AT-752 as a potential first antiviral treatment for dengue fever, the most prevalent mosquito-borne viral disease with a large global disease burden. We are planning to launch the Phase 2 trial for AT-752 in the first half of the year."

"Looking forward, we anticipate several important milestones and data readouts from our programs during the year. Importantly, we have the financial strength and a seasoned management team to advance these programs through key clinical and regulatory inflection points," concluded Dr. Sommadossi.

Bemnifosbuvir (AT-527) Program Update for COVID-19

Bemnifosbuvir Combination Program: Atea is conducting *in vitro* studies evaluating the combination of bemnifosbuvir with selected protease inhibitors to explore antiviral synergy and mitigation of potential viral drug resistance. Data from these ongoing *in vitro* studies will be the foundation for the Phase 2 clinical development of bemnifosbuvir in combination with a protease inhibitor.

Bemnifosbuvir Development Summary: In 2021, Atea reported data from two monotherapy Phase 2 clinical trials evaluating bemnifosbuvir for the treatment of COVID-19. One study was conducted in hospitalized adult high-risk patients with moderate COVID-19, while the second was conducted in adult outpatients with mild/moderate disease (MOONSONG). Although the Phase 2 MOONSONG trial did not meet its primary endpoint and the Phase 2 hospitalized study was closed out prior to completion, there were consistent positive trends in antiviral activity (~0.5 $\log_{10}$ reductions) observed after dosing with 550 mg twice daily (BID) and 1100 mg BID in sub-groups of patients at high risk for disease progression in exploratory analyses. In addition, results from a bronchoalveolar lavage study in healthy subjects showed that bemnifosbuvir was efficiently delivered to the lungs (epithelial lining fluid), the primary site of SARS-CoV-2 infection. Collectively, these data provide positive human proof-of-concept antiviral activity data that support a combination strategy.

In December 2021, Atea announced that based on the changing COVID-19 landscape, the global Phase 3 MORNINGSKY trial would be closed out and the focus of the COVID-19 program would shift to development of combination therapy with bemnifosbuvir as its backbone.

Publication of Bemnifosbuvir Mechanism Data in Peer-Reviewed Journal: In February 2022, new data highlighting bemnifosbuvir (AT-527) were published in the peer-reviewed journal *Nature Communications*. The published data demonstrate bemnifosbuvir's unique mechanism of action showing dual targets consisting of chain termination (RdRp) and nucleotidyltransferase (NiRAN) inhibition.

***In Vitro* Results Demonstrate AT-527 Is Active Against Different SARS-CoV-2 Variants:** AT-511, the free base of AT-527, has been shown to be a potent inhibitor of SARS-CoV-2 *in vitro*. Results evaluating antiviral activity against variants of concern and/or of interest, including Alpha, Gamma, Epsilon, Delta and others showed that AT-511 maintained its potency against all the variants tested to-date. These data confirm the key mechanistic advantage of the compound, which targets the highly conserved viral RNA polymerase.

Hepatitis C Virus (HCV) Program Update

Phase 2 HCV Combination Program: In January 2022, Atea announced that it had obtained exclusive worldwide rights to develop, manufacture and commercialize RZR, an oral NS5A inhibitor, through a license agreement with Merck. Atea plans to initiate a Phase 2 combination study of bemnifosbuvir and RZR in the second half of 2022. Studies conducted by Atea have shown *in vitro* synergy of the combination of bemnifosbuvir/RZR

in inhibiting HCV replication.

Since RZR is a Phase 2-ready NS5A inhibitor, Atea has prioritized clinical development of the bemnifosbuvir/RZR combination program due to its more advanced stage of development over the AT-777/AT-787 program. AT-777 was Atea's former lead NS5A inhibitor program, which was paused at the onset of COVID-19 due to industry-wide challenges impacting the conduct of clinical studies at that time.

RZR Development for HCV: RZR has demonstrated potent antiviral activity in the picomolar range in preclinical studies. Clinical studies of RZR conducted by Merck showed a > 3 $\log_{10}$ viral load decline in HCV-infected patients as monotherapy. In Merck studies, RZR was administered to over 1,200 HCV-infected patients at daily doses of up to 180 mg for up to 24 weeks. In these studies, RZR was generally well tolerated, and the overall safety data showed no consistent treatment-related changes in vital signs, electrocardiogram safety parameters or laboratory parameters. Atea believes RZR's pharmacokinetic (PK) profile supports once-daily dosing.

Bemnifosbuvir Development for HCV: In studies conducted by Atea, bemnifosbuvir 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 genotypes 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. Bemnifosbuvir has been shown to be generally well tolerated in more than 480 subjects (including healthy volunteers and patients with HCV or COVID-19). Atea believes bemnifosbuvir's PK profile supports once-daily dosing for the treatment of HCV.

Recent AT-752 Program Update

Phase 2 Dengue Program: Atea plans to initiate a Phase 2 clinical trial in dengue endemic countries and a human challenge study in the U.S. during the first half of 2022. Atea expects to report results from these studies in late 2022.

Successful Completion of Phase 1 Clinical Trial of AT-752: In December 2021, Atea completed a Phase 1 clinical trial demonstrating that AT-752 was well tolerated in 65 healthy subjects who were administered either single or multiple doses. No premature discontinuations due to adverse events or serious adverse events were reported. Most adverse events were mild and there were no changes in laboratory parameters.

Publication of *In Vitro* and *In Vivo* Data of AT-752 in Peer-Reviewed Journals: In August 2021, data demonstrating the *in vitro* and *in vivo* activity of AT-752 against dengue virus infection was published in the peer-reviewed journal *Antimicrobial Agents and Chemotherapy*. The published data show AT-752 had potent *in vitro* antiviral activity against all dengue virus serotypes and other flaviviruses tested. AT-752 was also shown to reduce viremia and improve animal health and survival in a mouse model of dengue virus.

In January 2022, data demonstrating the *in vivo* efficacy of AT-752 against yellow fever virus was published in the peer-reviewed journal PLOS Neglected Tropical Diseases. The published data show that AT-752 reduced viremia and improved disease outcomes in a hamster model of yellow fever virus.

Corporate Updates

Senior Management Appointment: In February 2022, Atea announced the appointment of Nancy Gail Berry Agrawal, PhD, as Executive Vice President of Preclinical Development. Prior to joining Atea, Dr. Agrawal spent more than 25 years in roles of increasing responsibility at Merck & Co. Inc., and most recently served as Vice President of Pharmacokinetics, Pharmacodynamics, and Drug Metabolism.

Strategic Collaboration: In November 2021, Atea announced that the strategic collaboration pursuant to which it was jointly developing bemnifosbuvir for the treatment of COVID-19 with Roche was being terminated. The termination was effective as February 10, 2022. As a result, the rights and licenses granted to Roche by Atea under the strategic collaboration have terminated and Atea has full rights to continue the clinical development and future commercialization of bemnifosbuvir on a worldwide basis.

Fourth Quarter and Full Year 2021 Financial Results

Cash and Cash Equivalents: $764.4 million at December 31, 2021 compared to $850.1 million at December 31, 2020.

Revenue: Collaboration revenue was $192.2 million and $351.4 million for the fourth quarter and full year 2021, respectively, compared to $48.6 million and $48.6 million for the corresponding periods in 2020. All collaboration revenue was derived from the Roche License Agreement, which was entered into in October 2020. Upon notice of termination in November 2021, the Company recognized all remaining deferred revenue related to the Roche License Agreement.

Research and Development Expenses: Research and development expenses were $57.8 million and $167.2 million for the fourth quarter and full year 2021, respectively, compared to $13.8 million and $38.0 million for the corresponding periods in 2020. The increase in research and development expenses was primarily due to an increase in external expenses related to the contract research organization and contract manufacturing organization services in conjunction with the advancement of product candidates for the treatment of COVID-19 and dengue fever. The research and development expenses include Atea's share of costs incurred by Roche and increases in internal spend primarily due to an increase in personnel-related expenses, including salaries, benefits and stock-based compensation expense for the Company's research and product development employees and consulting fees and other research and development expenses. In addition, the Company recorded a $25.0 million expense during the fourth quarter 2021 due to an upfront payment related to the in-license of ruzasvir from Merck.

General and Administrative Expenses: General and administrative expenses were $13.2 million and $45.8 million for the fourth quarter and full year 2021, respectively, compared to $14.1 million and $21.6 million for the corresponding periods in 2020. The increase in general and administrative expenses was primarily due to the expansion of the Company's organization and reflected an increase in payroll and personnel-related expenses, including salaries, benefits and stock-based compensation expense and other general and administrative expenses, partially offset by a $7.0 million fee paid during the fourth quarter of 2020 in connection with the Roche License Agreement.

Income Taxes: Income taxes were $4.1 million and $17.4 million for the fourth quarter and full year 2021, respectively, compared to $0 and $0 for the corresponding periods in 2020. The increase in income tax was primarily due to realization of income as a result of the recognition of revenue in 2021 associated with the Roche License Agreement.

Net Income (loss): Net income was $117.1 million and $121.2 million for the fourth quarter and full year 2021, compared to net income of $20.7

million and net loss of $10.9 million for the corresponding periods in 2020.

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

	Three Months Ended December 31,		Year Ended December 31,	
	2021 (unaudited)	2020 (unaudited)	2021 (unaudited)	2020
Collaboration revenue	$ 192,180	$ 48,633	$ 351,367	$ 48,633
Operating expenses				
Research and development	57,811	13,846	167,205	38,023
General and administrative	13,188	14,140	45,785	21,640
Total operating expenses	70,999	27,986	212,990	59,663
Income (loss) from operations	121,181	20,647	138,377	(11,030)
Interest income and other, net	51	9	213	83
Income (loss) before income taxes	121,232	20,656	138,590	(10,947)
Income taxes	4,100	—	17,400	—
Net income (loss) and comprehensive income (loss)	$ 117,132	$ 20,656	$ 121,190	$ (10,947)
Net income (loss) per share attributable to common stockholders				
Basic	$ 1.41	$ 0.37	$ 1.46	$ (0.51)
Diluted	$ 1.34	$ 0.25	$ 1.37	$ (0.51)
Weighted-average common shares outstanding				
Basic	83,095,320	56,198,542	82,820,037	21,592,441
Diluted	87,092,688	81,731,329	88,249,243	21,592,441

Selected Condensed Consolidated Balance Sheet Data
(in thousands except share and per share amounts)

	December 31, 2021 (unaudited)	December 31, 2020
Cash and cash equivalents	$ 764,375	$ 850,117
Working capital (1)	715,520	547,682
Total assets	772,892	863,632
Total liabilities	62,815	315,831
Total stockholder's equity	710,077	547,801

(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, 2021, to be filed February 28, 2022, 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 the fourth quarter and full year 2021 financial results and provide a corporate update today at 4:30 p.m. ET. To access the live conference call, please dial (833) 301-1150 (domestic) or (914) 987-7391 (international) at least five minutes prior to the start time and refer to conference ID 7171208.

A live audio webcast of the call and accompanying slide presentation will also be available in the Investors' Events & Presentations section of the Company's website, www.ateapharma.com. An archived webcast will be available on the Atea website approximately two hours after the event.

About Atea Pharmaceuticals

Atea Pharmaceuticals is a clinical stage biopharmaceutical company focused on discovering, developing and commercializing oral therapies to address the unmet medical needs of patients with life-threatening viral diseases. Leveraging the Company's deep understanding of antiviral drug development, nucleos(t)ide chemistry, biology, biochemistry and virology, Atea has built a proprietary nucleotide prodrug platform to develop novel product candidates to treat single stranded ribonucleic acid, or ssRNA, viruses, which are a prevalent cause of severe viral diseases. Atea plans to continue to build out 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 difficult-to-treat, life-threatening viral infections, including severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), the virus that causes COVID-19, hepatitis C virus (HCV), dengue virus and respiratory syncytial virus (RSV). For more information, please visit www.ateapharma.com.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements contained in this press release that do not relate to matters of historical fact should be considered forward-looking statements, including without limitation statements regarding our expectations surrounding the potential of our product candidates, including bemnifosbuvir combination product candidates and AT-752, and expectations regarding our pipeline, including trial design and development timelines. These statements are neither promises nor guarantees, but involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements, including, but not limited to, the following: uncertainty around and costs associated with the development of AT-752 as a potential treatment for dengue and combination product candidates including bemnifosbuvir for the potential treatment for COVID-19 and HCV; dependence on management, directors and other key personnel; the impact of the COVID-19 pandemic on our business; our limited operating history and no history of successfully developing or commercializing any products, significant operating expenses since inception; our need for substantial additional funding; our ability to use our net operating loss carryforwards; our dependence on the success of our most advanced product candidates; risks related to the regulatory approval process; risks associated with the clinical development process and reliance on interim, topline or preliminary clinical trial results; risks related to healthcare laws and other legal compliance matters; risks related to potential commercialization; risks related to manufacturing and our dependence on third parties; risks relating to intellectual property; our ability to maintain effective internal control over financial reporting and the significant costs as a result of operating as a public company. These and other important factors discussed under the caption “Risk Factors” in our Annual Report on Form 10-K for the year ended December 31, 2021 and our other filings with the SEC 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 we may elect to update such forward-looking statements at some point in the future, we disclaim any obligation to do so, even if subsequent events cause our views to change.

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