Athira Pharma Reports Third Quarter 2022 Financial Results and Recent Clinical and Corporate Updates

November 10, 2022

Independent, unblinded, interim efficacy and futility analysis of Phase 2/3 LIFT-AD study in mild-to-moderate Alzheimer's disease patients supports potential clinically meaningful activity of fosgonimeton without background acetylcholinesterase therapy and mitigates program risk

Strong balance sheet to support clinical development pipeline through key data inflection points

BOTHELL, Wash., Nov. 10, 2022 (GLOBE NEWSWIRE) -- Athira Pharma, Inc. (NASDAQ: ATHA), a late clinical-stage biopharmaceutical company focused on developing small molecules to restore neuronal health and slow neurodegeneration, today announced the company's financial results for the third quarter ended September 30, 2022 and reviewed recent clinical and corporate updates.

"During the third quarter, we undertook a systematic and data-driven process to determine the next steps for our Phase 2/3 LIFT-AD study of fosgonimeton in mild-to-moderate Alzheimer's disease (AD) patients. Most recently, we were encouraged to report that an independent, unblinded, interim efficacy and futility analysis supported the potential clinically meaningful activity of fosgonimeton without background therapy (acetylcholinesterase inhibitors) and determined that, with the additional enrollment of fewer than 150 patients, the study will be well powered for the primary endpoint given the preliminary effect size observed," stated Mark Litton, Ph.D., President and Chief Executive Officer of Athira.

"The exploratory Phase 2 ACT-AD study in the same patient population suggested benefits in measurements of cognition, function and neuroprotection, and the results of the LIFT-AD interim analysis corroborate those findings in approximately 100 patients not on background therapy. We now look forward to completing enrollment of the Phase 2/3 LIFT-AD study in mid-2023 and to reporting topline data in early 2024. Importantly, we are pleased to have a strong balance sheet that can support our programs through a number of key data inflection points and beyond," concluded Dr. Litton.

Clinical Update:

Fosgonimeton (ATH-1017) is a small molecule specifically designed to enhance the activity of Hepatocyte Growth Factor (HGF) and its receptor, MET.

LIFT-AD Phase 2/3 study in mild-to-moderate Alzheimer's disease (NCT04488419)

- Following results from the exploratory ACT-AD trial, Athira proactively amended the entry criteria for the LIFT-AD trial in September 2022 to investigate the effects of fosgonimeton compared with placebo, without background therapy. In October 2022, following an unblinded interim efficacy and futility analysis, an independent data monitoring committee recommended continuation of the LIFT-AD study of fosgonimeton in patients with mild-to-moderate AD. The committee also determined that, with the additional enrollment of fewer than 150 patients for a total enrollment of less than 300 patients without background therapy, the study will be well powered for the primary endpoint given the preliminary effect size observed.

ACT-AD Phase 2 study in mild-to-moderate Alzheimer's disease (NCT04491006)*

- Additional data from the ACT-AD Phase 2 study were presented in August 2022 at the Alzheimer's Association International Conference 2022 (AAIC). This included a numerical, but not statistically significant, improvement in the secondary endpoint ADCS-ADL23, a functional measure of independence, and a statistically significant improvement in plasma levels of neurofilament light chain (NfL), a validated fluid biomarker of neurodegeneration, in a prespecified subgroup of subjects treated with fosgonimeton without background therapy compared with placebo at 26 weeks.

Open Label Extension (OLEX) study (NCT04886063)

- The Open Label Extension (OLEX) study for the ACT-AD and LIFT-AD studies continues, with over 200 patients currently enrolled. As of October 2022, more than 90 percent of patients who have completed either study have elected to participate in the OLEX study.

SHAPE Phase 2 study in Parkinson's disease dementia or Dementia with Lewy bodies (NCT04831281)

- The SHAPE Phase 2 proof-of-concept study of fosgonimeton in participants with Parkinson's disease dementia or Dementia with Lewy bodies is approximately 40% enrolled.
- The company is evaluating next steps for this program in light of the ACT-AD results and the interim LIFT-AD analysis.

ATH-1020 is an orally available, brain-penetrant small molecule designed to enhance the HGF/MET system that is being advanced as a potential treatment candidate for neuropsychiatric indications.

Phase 1 study of ATH-1020 in healthy volunteers (NCT05169671)

- Athira is conducting a Phase 1 study to evaluate the safety, tolerability, and pharmacokinetics of ATH-1020 in approximately 68 healthy young and elderly volunteers. The single ascending dose escalation portion of the trial has been completed with no safety findings.

Research and Development Update:

***Preclinical data presented at* Alzheimer's Association International Conference (AAIC) 2022**

- Preclinical data presented at the AAIC conference in August 2022 demonstrated that fosgo-AM, the active metabolite of fosgonimeton, can promote neurotrophic effects and offer protection against neurological insults central to neurodegeneration in animal models of Alzheimer's disease. Additional data presented highlighted the ability of new orally available small molecule positive modulators of HGF/MET to reverse memory deficits in preclinical models.

Upcoming data presentations at scientific meetings

- At the Society for Neuroscience 2022 Annual Meeting (November 12-16, 2022; San Diego), Athira will present data highlighting the effects of fosgonimeton in preclinical models of Parkinson's disease as well as preclinical data on small molecule positive modulators of HGF/MET in diabetic neuropathic pain.
- At the 15th Clinical Trials on Alzheimer's Disease (CTAD) Annual Meeting (November 29-December 2, 2022; San Francisco), Athira will give a poster presentation on fosgonimeton's effect on additional plasma biomarkers from the ACT-AD study and their relevance to clinical endpoints.
- At the 33rd International Symposium on Amyotrophic Lateral Sclerosis and Motor Neuron Disease (December 6-9, 2022; virtual), Athira will present preclinical data demonstrating neuroprotective effects of ATH-1105, a small molecule positive modulator of HGF/MET, in an animal model of Amyotrophic Lateral Sclerosis (ALS).

Financial Results

- **Cash Position**. Cash, cash equivalents and investments were $260.0 million as of September 30, 2022, compared with $319.7 million as of December 31, 2021. Cash used in operations was $56.8 million for the nine months ended September 30, 2022, compared with $24.9 million for the nine months ended September 30, 2021.

- **Research and Development (R&D) Expenses**. R&D expenses were $17.0 million for the quarter ended September 30, 2022, compared with $10.7 million for the same period in 2021. The increase was driven primarily by costs related to increased clinical trial activities, expanded personnel, and increased preclinical research and development expenses.

- **General and Administrative (G&A) Expenses.** G&A expenses were $7.2 million for the quarter ended September 30, 2022, compared with $7.1 million for same period in 2021.

- **Net Loss**. The company reported a net loss of $20.2 million, or $0.53 per share, for the quarter ended September 30, 2022, compared with a net loss of $15.7 million, or $0.42 per share, for the same period in 2021.

About Athira Pharma, Inc.
Athira Pharma, Inc., headquartered in the Seattle, Washington area, is a late clinical-stage biopharmaceutical company focused on developing small molecules to restore neuronal health and slow neurodegeneration. Athira aims to provide rapid cognitive improvement and alter the course of neurological diseases with its novel mechanism of action. Athira is currently advancing its pipeline of therapeutic candidates targeting the HGF/MET neurotrophic system for Alzheimer's disease, Parkinson's disease dementia, Dementia with Lewy bodies, and neuropsychiatric indications. For more information, visit www.athira.com. You can also follow Athira on Facebook, LinkedIn and @athirapharma on Twitter and Instagram.

*The ACT-AD trial was supported by a grant from the National Institute on Aging of the National Institutes of Health under Award Number R01AG06268. The information presented in this press release is solely the responsibility of Athira and does not necessarily represent the official views of the National Institutes of Health.

Forward-Looking Statements
This communication contains "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, Section 21E of the Securities Exchange Act of 1934 and the Private Securities Litigation Reform Act of 1995. These forward-looking statements are not based on historical fact and include statements regarding fosgonimeton as a potential treatment for Alzheimer's disease, Parkinson's disease dementia, Dementia with Lewy bodies, and other dementias; ATH-1020 as a potential treatment for neuropsychiatric indications; Athira's platform technology and potential therapies; future development plans; clinical and regulatory objectives and the timing thereof; expectations regarding the potential efficacy and commercial potential of Athira's product candidates; the anticipated reporting of data; the potential learnings from the ACT-AD trial and LIFT-AD unblinded interim efficacy and futility analysis and their ability to inform and improve future clinical development plans; and Athira's ability to advance its product candidates into later stages of development. Forward-looking statements generally include statements that are predictive in nature and depend upon or refer to future events or conditions, and include words such as "may," "will," "should," "on track," "would," "expect," "plan," "believe," "intend," "pursue," "continue," and other similar expressions, among others. Any forward-looking statements are based on management's current expectations of future events and are subject to a number of risks and uncertainties that could cause actual results to differ materially and adversely from those set forth in or implied by such forward-looking statements. These risks and uncertainties include, but are not limited to, the data for our product candidates from or preclinical and clinical trials will not support the safety, efficacy and tolerability of our product candidates; cessation or delay of any of the ongoing clinical trials and/or Athira's development of fosgonimeton and other product candidates may occur; regulatory authorities could

object to protocols, amendments and other submissions; future potential regulatory milestones of fosgonimeton and other product candidates, including those related to current and planned clinical studies, may be insufficient to support regulatory submissions or approval; the impact of the COVID-19 pandemic on Athira's business, research and clinical development plans and timelines, and the regulatory process for Athira product candidates; Athira may not be able to recruit sufficient patients for its clinical trials; the outcome of legal proceedings that have been or may in the future be instituted against us and certain of our directors and officers; clinical trials may not demonstrate safety and efficacy of any of Athira's product candidates; possible negative interactions of Athira's product candidates with other treatments; Athira's assumptions regarding the sufficiency of its cash, cash equivalents and investments to fund its planned operations may be incorrect; adverse conditions in the general domestic and global economic markets; the impact of competition; regulatory agencies may be delayed in reviewing, commenting on or approving any of Athira's clinical development plans as a result of the COVID-19 pandemic, which could further delay development timelines; the impact of expanded product development and clinical activities on operating expenses; the impact of new or changing laws and regulations; as well as the other risks detailed in Athira's filings with the Securities and Exchange Commission. These forward-looking statements speak only as of the date hereof and Athira undertakes no obligation to update forward-looking statements. Athira may not actually achieve the plans, intentions, or expectations disclosed in its forward-looking statements, and you should not place undue reliance on the forward-looking statements.

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Athira Pharma, Inc.
Condensed Consolidated Balance Sheets
(Amounts in thousands)

	September 30, 2022	December 31, 2021
	(unaudited)	
Assets		
Cash and cash equivalents	$ 87,049	$ 110,537
Short-term investments	133,913	143,222
Other short-term assets	8,010	7,040
Long-term investments	39,071	65,936
Other long-term assets	6,142	5,273
Total assets	$ 274,185	$ 332,008
Liabilities and stockholders' equity		
Current liabilities	$ 10,264	$ 9,292
Long-term liabilities	1,672	1,632
Total liabilities	11,936	10,924
Stockholders' equity	262,249	321,084
Total liabilities and stockholders' equity	$ 274,185	$ 332,008

Athira Pharma, Inc.
Condensed Consolidated Statements of Operations and Comprehensive Loss
(Amounts in thousands, except share and per share amounts)
(Unaudited)

	Three Months Ended September 30,	
	2022	2021
Operating expenses:		
Research and development	$ 16,965	$ 10,707
General and administrative	7,168	$ 7.119
Total operating expenses	24,133	17,826
Loss from operations	(24,133)	(17,826)
Grant income	2,959	2,079
Other income, net	985	73
Net loss	$ (20,189)	$ (15,674)
Unrealized loss on available-for-sale securities	(547)	(33
Comprehensive loss attributable to common stockholders	$ (20,736)	$ (15,707)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.53)	$ (0.42)

Weighted-average shares used in computing net loss per share attributable to common stockholders, basic and diluted	37,817,724	37,312,356