Athira Pharma Provides 2024 Clinical Pipeline Outlook and Business Update

January 8, 2024

Completed enrollment in Phase 2/3 LIFT-AD clinical trial of fosgonimeton as a potential treatment for mild-to-moderate Alzheimer's disease and expects topline data in second half of 2024

Plans to initiate first-in-human studies of ATH-1105 to treat amyotrophic lateral sclerosis in first half of 2024

BOTHELL, Wash., Jan. 08, 2024 (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 provided a clinical pipeline outlook and business update for 2024.

"The new year is off to a strong start with the completion of enrollment in our Phase 2/3 LIFT-AD clinical trial of fosgonimeton as a potential treatment for mild-to-moderate Alzheimer's disease (AD), which we expect will enable topline data readout from the study in the second half of 2024," said Mark Litton, Ph.D., President and Chief Executive Officer of Athira. "The potential of fosgonimeton as a treatment for AD is supported by the independent, unblinded interim efficacy and futility analysis of the first 100 subjects in the Phase 2/3 LIFT-AD study and the results from the exploratory Phase 2 ACT-AD clinical trial, which showed potential congruent improvements in biomarkers of neurodegeneration, inflammation and Alzheimer's disease protein pathologies as well as measures of cognition and function."

"The totality of data shared to date strengthens our confidence in and supports the potential of our small molecule approach to targeting the neurotrophic hepatocyte growth factor (HGF) system for diseases including Alzheimer's, Parkinson's, and amyotrophic lateral sclerosis (ALS). The consistency of data from preclinical models across various neurodegenerative diseases and in Alzheimer's patients suggests that our small molecule drug candidates may be neuroprotective, neurotrophic, procognitive and potentially disease-modifying. This includes our recently reported findings from the exploratory SHAPE Phase 2 clinical trial, the results of which showed positive effects on several cognitive measures in the fosgonimeton 40 mg dose group, which is the same dose being investigated in the LIFT-AD trial."

"We look forward to an exciting year ahead with key preclinical and clinical milestones on the horizon. Importantly, we continue to advance and expand our understanding of the potential for modulating the neurotrophic HGF system and have a strong balance sheet to support these initiatives through key inflection points."

"Finally, I want to thank Dr. Hans Moebius for his considerable contributions as Athira's Chief Medical Officer and congratulate him on his retirement. In addition to his five years with Athira, Hans has more than 30 years of industry experience and is an internationally recognized expert in neuropsychiatry, drug research and development, and regulatory strategy. We look forward to a continued relationship with Hans in his new role as Senior Scientific Advisor to Athira," added Dr. Litton.

Athira's 2024 Clinical Pipeline Outlook: Status and Upcoming Milestones

Athira's drug development pipeline consists of potential first-in-class (fosgonimeton) and next-generation small molecule therapeutic candidates (ATH-1105 and ATH-1020) designed to promote the neurotrophic HGF system, which activates neuroprotective, neurotrophic and anti-inflammatory pathways in the central nervous system. Athira's therapeutic candidates have distinct properties, which the Company believes may be applicable to a broad range of neurodegenerative diseases.

Fosgonimeton (ATH-1017) – A potentially first-in-class, once daily, subcutaneously administered drug candidate initially targeted for the potential treatment of Alzheimer's disease.

LIFT-AD Phase 2/3 clinical trial of fosgonimeton in mild-to-moderate Alzheimer's disease (NCT04488419)

- The LIFT-AD study is investigating the effects of fosgonimeton 40 mg compared with placebo in mild-to-moderate AD patients who are not receiving 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 in patients with mild-to-moderate AD who are not receiving background therapy. The committee also determined that the study would be well powered to achieve the primary endpoint with approximately 300 patients given the preliminary effect size observed in the unblinded interim analysis of approximately 100 patients treated.
- In May 2023, Athira selected the 40 mg dose for further development and potential regulatory approval.
- In January 2024, Athira announced completion of enrollment in the LIFT-AD study, ultimately randomizing approximately 315 patients in the primary analysis population.
- The Company expects to report topline data in the second half of 2024.

Open Label Extension (OLEX) fosgonimeton trial (NCT04886063)

- Eligible participants who complete the LIFT-AD or ACT-AD trials and elect to participate in the ongoing OLEX are able to receive up to 30 months of open-label treatment.
- Greater than 85% of participants who completed either study have elected to enroll in OLEX to date.
- Currently more than 60 patients are continuing fosgonimeton treatment beyond 18 months, which is unexpected in a progressive mild-to-moderate Alzheimer's disease population.
- Athira believes OLEX will complement its long-term safety database and provide insights into fosgonimeton's long-term effects for up to three years of investigational treatment.

SHAPE Phase 2 clinical trial of fosgonimeton in mild-to-moderate Parkinson's disease dementia and Dementia with Lewy bodies (NCT04831281)

- In December 2023, Athira announced encouraging results from the exploratory SHAPE Phase 2 clinical trial of fosgonimeton for the potential treatment of Parkinson's disease dementia and Dementia with Lewy bodies.
- Treatment with fosgonimeton 40 mg (n=5) compared to placebo (n=7) showed positive effects in cognitive measures including ADAS-Cog13, MMSE, and COWAT over the 6-month double-blind treatment period.
- The primary endpoint, a composite score of the change in Event-Related-Potential (ERP) P300 latency and cognitive assessment (ADAS-Cog13), was not met compared with placebo.
- Fosgonimeton was generally well tolerated, with a favorable safety profile. There were no treatment-related serious adverse events observed in the study. The most common adverse event in the treatment groups was injection site reactions.

ATH-1105 – A next-generation, orally administered drug candidate developed for the potential treatment of amyotrophic lateral sclerosis as the Company's initial indication.

- ATH-1105's potential as a treatment for ALS is supported by a growing body of preclinical evidence demonstrating statistically significant improvements on nerve and motor function, biomarkers of inflammation and neurodegeneration, and survival in various ALS animal models.
- These data were presented throughout 2023 at a variety of key scientific and medical meetings including the American Association of Neurology (AAN), the Alzheimer's Association International Congress (AAIC), the Northeast Amyotrophic Lateral Sclerosis Consortium® (NEALS), and the Motor Neurone Disease Association (MNDA).
- The initiation of first-in-human studies of ATH-1105 is targeted for the first half of 2024 to evaluate this promising drug candidate as a treatment for ALS.

Management Team Update
Hans Moebius, MD, PhD, is retiring as Chief Medical Officer effective January 5, 2024, and will continue as Athira's Senior Scientific Advisor. The Company has initiated a search to fill the Chief Medical Officer position.

Financial Position
Athira has unaudited cash, cash equivalents and investments of approximately $147.4 million as of December 31, 2023, to support the advancement of the Company's innovative pipeline through key inflection points.

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 alter the course of neurological diseases by advancing its pipeline of therapeutic candidates that modulate the neurotrophic HGF system. For more information, visit www.athira.com. You can also follow Athira on Facebook, LinkedIn, X (formerly known as Twitter) and Instagram.

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: product candidates as a potential treatment for Alzheimer's disease, Parkinson's disease, Parkinson's disease dementia, Dementia with Lewy bodies, and other neurodegenerative diseases, such as amyotrophic lateral sclerosis; future development plans; the anticipated reporting of data; the potential learnings from the ACT-AD and SHAPE trials and LIFT-AD unblinded interim efficacy and futility analysis and their ability to inform and improve future clinical development plans; expectations regarding the potential efficacy and commercial potential of Athira's product candidates; preliminary and unaudited estimates of Athira's cash, cash equivalents, and investments; 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," "suggest," "potential," and similar expressions. 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 from preclinical and clinical trials may not support the safety, efficacy and tolerability of Athira's product candidates; development of product candidates may cease or be delayed; regulatory authorities could object to protocols, amendments and other submissions; future potential regulatory milestones for product candidates, including those related to current and planned clinical studies, may be insufficient to support regulatory submissions or

approval; 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 Athira, its directors and officers; possible negative interactions of Athira's product candidates with other treatments; Athira's assumptions regarding its financial condition and 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 pandemics or health epidemics, 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 from time to time. 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. Furthermore, Athira is in the process of finalizing its financial results for the fourth quarter and fiscal year ended December 31, 2023, and therefore such finalized and audited results and final analysis of those results are not yet available. The preliminary expectations regarding year-end cash, cash equivalents, and investments are the responsibility of management, are subject to management's review, and actual results could differ from management's expectations. The actual results are also subject to audit by Athira's independent registered public accounting firm and no assurance is given by its independent registered public accounting firm on such preliminary expectations. No conclusions should be made as to any other financial results as of and for the year ended December 31, 2023, based on the foregoing estimates.

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