



Athira Pharma Extends Ongoing Open Label Extension Study for LIFT-AD and ACT-AD Clinical Trials of Fosgonimeton (ATH-1017) for Mild to Moderate Alzheimer's Disease

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– Study duration increased from 6 months to 18 months of open label treatment with fosgonimeton –

BOTHELL, Wash., May 09, 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 that it is extending the length of the current open label extension (OLEX) study for its Phase 3 LIFT-AD and Phase 2 ACT-AD studies of fosgonimeton for the treatment of mild-to-moderate Alzheimer's disease. This decision is in alignment with the independent Data and Safety Monitoring Board (DSMB) following its most recent review of available data. Eligible subjects who have completed the LIFT-AD or ACT-AD trials and elect to participate in the ongoing open label extension may now receive up to 18 months of open-label treatment.

"This additional treatment extension allows us to meet investigator and patient interest in continuing treatment with fosgonimeton beyond the initial 6 months offered," said Hans Moebius, M.D., Ph.D., Chief Medical Officer at Athira. "We are confident that the approach to the extension balances patient and investigator perspectives with a thorough safety review in consultation with our DSMB. To date, the majority of LIFT-AD and ACT-AD study participants are continuing on the open label extension, and we are pleased to offer them an opportunity to maintain their access to fosgonimeton."

The LIFT-AD and ACT-AD trials are both randomized, double-blind, placebo-controlled, parallel-group 26-week trials evaluating fosgonimeton for the treatment of mild-to-moderate Alzheimer's disease. Patients are stratified 1:1:1 to receive low dose fosgonimeton (40 mg/day), high dose fosgonimeton (70 mg/day) or placebo.

The composite primary endpoint for LIFT-AD is the Global Statistical Test and co-key secondary endpoints include cognition, function and behavior. ACT-AD is powered for its primary endpoint, Event-Related-Potential (ERP) P300 Latency, a functional measure of working memory processing speed and executive function, which highly correlates with cognition. Secondary endpoints include cognition, function, and behavior. Topline data of LIFT-AD are targeted in the first half of 2023 and of ACT-AD by the end of the second quarter of 2022.

Following completion of the 26-week treatment period during the LIFT-AD or ACT-AD trials, eligible patients may elect to continue on the open label extension and receive treatment with fosgonimeton at the high dose (70 mg/day) for up to an additional 18 months. Investigators and patients will remain blinded to treatment group assignment in the parent trials.

For more information on the LIFT-AD or ACT-AD* trials, visit www.lift-adtrial.com or www.act-adtrial.com. For more information on this open-label extension study, refer to [NCT04886063](https://clinicaltrials.gov/ct2/show/study/NCT04886063) or visit athiraclinicaltrials.com/OLEX.

*The ACT-AD trial is 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.

About Fosgonimeton (ATH-1017)

Fosgonimeton (ATH-1017) is a small molecule designed to enhance the activity of hepatocyte growth factor (HGF) and its receptor, MET, to impact neurodegeneration and regenerate brain tissue. The function of the HGF/MET receptor system may be impaired in the brain under conditions of neurodegeneration. In addition to Alzheimer's disease, fosgonimeton has the potential to address the broader dementia population, including Parkinson's disease dementia and Dementia with Lewy bodies, as the mode of action focuses on network recovery and synaptic signal transmission in the brain.

About Athira Pharma, Inc.

Athira, headquartered in the Seattle 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 therapeutic candidates, targeting the HGF/MET neurotrophic system, for Alzheimer's and 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](https://www.facebook.com/athirapharma), [LinkedIn](https://www.linkedin.com/company/athirapharma) and @athirapharma on [Twitter](https://twitter.com/athirapharma) and [Instagram](https://www.instagram.com/athirapharma).

Forward-Looking Statements

This release 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 and Dementia with Lewy bodies, and other dementias; 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; 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 preliminary data for Athira’s fosgonimeton product candidate from the Phase 1a/b trials will not continue or persist in current or planned clinical trials; cessation or delay of any of the ongoing clinical trials and/or Athira’s development of fosgonimeton and other product candidates may occur; future potential regulatory milestones of our 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 results of operations, including impact on Athira’s clinical trial sites and contractors who act for or on Athira’s behalf, may be more severe and more prolonged than currently anticipated; the regulatory process for Athira product candidates; the outcome of legal proceedings which 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; Athira’s research and development efforts and its ability to advance product candidates into later stages of development may fail; any one or more of Athira’s product candidates may not be successfully developed, approved or commercialized; 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; Athira’s assumptions regarding the sufficiency of its cash, cash equivalents and investments to fund its planned operations may be incorrect; while P300 latency is a functional measure that is highly correlated with cognition, Athira may not successfully establish a connection between these P300 latency results and improved cognition; 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.

Investor & Media Contact:

Julie Rathbun

Athira Pharma

Julie.rathbun@athira.com

206-769-9219