Athira Pharma Advances Phase 2/3 LIFT-AD Clinical Study of Fosgonimeton in Mild-to-Moderate Alzheimer's Patients Following Independent, Unblinded Interim Analysis

October 17, 2022

Results support potential clinically meaningful activity of fosgonimeton without background therapy and mitigate program risk

Updated study well powered for primary endpoint with addition of fewer than 150 patients

Company targets completion of enrollment in mid-2023 and topline results in early 2024

Company to host live webcast today at 8:30 a.m. Eastern

BOTHELL, Wash., Oct. 17, 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 following an unblinded interim efficacy and futility analysis, an independent data monitoring committee recommended continuation of the LIFT-AD study of fosgonimeton (ATH-1017) in patients with mild-to-moderate Alzheimer's disease (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 (acetylcholinesterase inhibitors), the study will be well powered for the primary endpoint given the preliminary effect size observed. The primary endpoint of LIFT-AD is the Global Statistical Test, an unweighted composite score comprising measures of cognition (Alzheimer's Disease Assessment Scale-Cognitive Subscale [ADAS-Cog11]) and function (Alzheimer's Disease Cooperative Study-Activities of Daily Living [ADCS-ADL23]).

Results from the completed exploratory ACT-AD Phase 2 study showed a favorable safety profile and suggested positive effects on measures of cognition (ADAS-Cog11), function (ADCS-ADL23) and neurodegeneration (plasma neurofilament light chain or NfL) in patients taking fosgonimeton without background therapy. Guided by these results, the Company proactively amended LIFT-AD to focus on patients not on background therapy. The unblinded interim analysis was then conducted in approximately 100 patients not on background therapy to corroborate observations from ACT-AD and ensure LIFT-AD is well powered to determine the effect of fosgonimeton on clinically meaningful and commercially relevant endpoints.

"The results from the data monitoring committee's unblinded analysis give us confidence in a potentially positive outcome for LIFT-AD, as stringent evaluation criteria were applied based on validated and clinically meaningful cognitive and functional outcomes," said Hans Moebius, M.D., Ph.D., Chief Medical Officer of Athira. "This analysis supports the potential clinical benefits of fosgonimeton treatment and underscores the rationale for continued development of this promising new therapy."

"We are very excited by the results of this independent review as we believe they mitigate the risk of the fosgonimeton development plan, support the potential clinical benefit of fosgonimeton and inform the sample size needed to achieve success with LIFT-AD," said Mark Litton, Ph.D., President and Chief Executive Officer of Athira. "We are now targeting to complete enrollment in mid-2023 and report topline data in early 2024. Importantly, we have a strong balance sheet to execute our plans through key data readouts and beyond. Moving forward, we remain keenly focused on advancing this novel investigational therapy with the hope of positively impacting the lives of millions of Alzheimer's patients.

"Our goal with fosgonimeton is to demonstrate its ability to improve cognition and function and to ultimately provide neuroprotection. The ACT-AD study suggested these benefits, and the results of the LIFT-AD interim analysis corroborate those findings," added Dr. Litton. "We believe any drug that can demonstrate neuroprotection could become a treatment of choice for mild-to-moderate Alzheimer's patients."

Live Webcast
Athira will host a live webcast to discuss the LIFT-AD interim analysis in greater detail at 8:30 a.m. Eastern Time today, Monday, Oct. 17, 2022. To access the live webcast, please visit https://us02web.zoom.us/webinar/register/WN_AtJ3jqG1RtmRRlcU_cYb-Q or the "Events and Presentations" page within the Investors section of the Athira website: https://investors.athira.com/news-and-events/events-and-presentations-investor. An archived replay will also be available on the website for at least 90 days following the event.

About the LIFT-AD Clinical Study
LIFT-AD is a randomized, double-blind, placebo-controlled, parallel-group study of fosgonimeton for patients with mild-to-moderate Alzheimer's disease. Patients are randomized across two dose groups and one placebo group on a 1:1:1 basis to receive a subcutaneous injection of fosgonimeton or placebo once daily over a treatment course of 26 weeks. The primary endpoint for LIFT-AD is the Global Statistical Test, an unweighted composite score comprising measures of cognition (Alzheimer's Disease Assessment Scale-Cognitive Subscale [ADAS-Cog11]) and function (Alzheimer's Disease Cooperative Study-Activities of Daily Living [ADCS-ADL23]). Additional information on the LIFT-AD study can be found at: NCT04488419.

About Fosgonimeton
Fosgonimeton 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.

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.

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 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, LinkedIn and @athirapharma on 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 fosgonimeton as a potential treatment for Alzheimer's disease, Parkinson's disease dementia, 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; 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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