Athira Pharma Announces Last Patient Completed LIFT-AD Clinical Trial of Fosgonimeton in Mild-to-Moderate Alzheimer's Disease

July 9, 2024

Reporting of Topline Results Targeted by End of Third Quarter 2024

Results to be presented in oral presentation at Clinical Trials on Alzheimer's Disease (CTAD) on October 29, 2024, in Madrid, Spain

BOTHELL, Wash., July 09, 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 announced the completion of dosing for the last patient in the Phase 2/3 LIFT-AD clinical trial evaluating fosgonimeton in people with mild-to-moderate Alzheimer's disease (AD). The Company is now targeting to report topline results from the LIFT-AD trial by the end of the third quarter of 2024 and has been invited to discuss the fuller data set during an oral presentation on October 29, 2024, at the 17th Clinical Trials on Alzheimer's Disease (CTAD) conference taking place from October 29 – November 1, 2024, in Madrid, Spain.
LIFT-AD (NCT04488419) is a randomized, placebo-controlled, double-blind study evaluating the efficacy and safety of fosgonimeton, which is designed to positively modulate the neurotrophic hepatocyte growth factor (HGF) system to protect and preserve neuronal health and function. The trial enrolled approximately 315 patients not on acetylcholinesterase inhibitors (AChEIs) with mild-to-moderate AD to evaluate once-daily subcutaneous injections of fosgonimeton 40 mg compared to placebo over a 26-week treatment period. The primary endpoint of LIFT-AD is the change from baseline after 26 weeks of treatment using the Global Statistical Test (GST), a combination of results from measures of cognition (ADAS-Cog11) and function (ADCS-ADL23).

"With patient dosing now complete, we eagerly look forward to the readout of topline results from the LIFT-AD trial, which is targeted by the end of September. The trial's primary endpoint, GST, will assess the treatment effects of fosgonimeton across multiple aspects of the disease," said Javier San Martin, M.D., Chief Medical Officer of Athira. "Both of the clinical assessments that comprise GST, ADAS-Cog11 and ADCS-ADL23, are widely used in AD trials and are accepted endpoints by the U.S. Food and Drug Administration and other regulatory bodies. Importantly, GST evaluates cognition and function, two key measures of disease progression, which gives us confidence that this endpoint will provide an understanding of the impact of relevant clinical outcomes that fosgonimeton may have in AD. Additionally, the trial will measure serum biomarkers, which will provide insights into the potential neuroprotective mechanism and disease modifying effects of fosgonimeton. We would like to extend our thanks to the investigators, their staff, patients and caregivers involved in the LIFT-AD trial."

Notably, 85% of eligible clinical trial participants in LIFT-AD and the Phase 2 ACT-AD trial elected to enroll in Athira's open label extension study (OLEX), which enables participants to either remain on fosgonimeton or, for those in the placebo group, begin fosgonimeton treatment. Currently, more than 70 patients are continuing fosgonimeton treatment beyond 18 months, with nearly 50 patients beyond two years, reflecting a long-term participation rate beyond what might be expected in a progressive mild-to-moderate Alzheimer's disease population.

"We are excited to reach this milestone in the LIFT-AD trial and, more importantly, to be closer to data readout when we hope to demonstrate the potential of fosgonimeton as a differentiated approach to the treatment of Alzheimer's disease," said Mark Litton, Ph.D., President and Chief Executive Officer of Athira. "Patients are in need of better therapies, and we believe that fosgonimeton, acting on the naturally occurring neurotrophic HGF system, offers the potential to be a first-in-class therapeutic that may impact the course of Alzheimer's disease by activating neuroprotective, neurotrophic and anti-inflammatory pathways in the central nervous system."

Athira management recently hosted a Key Opinion Leader event focusing on GST, the primary endpoint of the LIFT-AD clinical trial, which Athira believes is a comprehensive measure of overall disease impact and the potential for fosgonimeton to protect and preserve neuronal health in mild-to-moderate AD patients. The webcast event featured presentations from Suzanne Hendrix, Ph.D., Founder and CEO of Pentara Corporation, and Anton P. Porsteinsson, M.D., Director of the University of Rochester Alzheimer's Disease Care, Research, and Education Program (AD-CARE). A replay of the event can be accessed here.

About Fosgonimeton
Fosgonimeton is a potentially first-in-class, once daily, subcutaneously administered small molecule drug candidate. Targeting the protection and repair of neuronal networks, fosgonimeton has disease-modifying potential to address a broad range of neurodegenerative diseases, including Alzheimer's disease, Parkinson's disease, and dementia with Lewy bodies.

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, including fosgonimeton, which is being evaluated for the potential treatment of mild-to-moderate Alzheimer's disease in the Phase 2/3 LIFT-AD trial that is targeted to report topline data by the end of the third quarter of 2024. 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: Athira’s drug candidates as potential treatments for Alzheimer’s disease, Parkinson’s disease, dementia with Lewy bodies, and other neurodegenerative diseases; future development plans; the anticipated reporting of data; the potential learnings from preclinical studies and other nonclinical data and their ability to inform and improve future clinical development plans; expectations regarding the potential efficacy and commercial potential of Athira’s drug candidates; and Athira’s ability to advance its drug 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 drug candidates; development of drug candidates may cease or be delayed; regulatory authorities could object to protocols, amendments and other submissions; future potential regulatory milestones for drug candidates, including those related to current and planned clinical studies, may be insufficient to support regulatory submissions or approval; the anticipated timing of the topline data from the LIFT-AD trial may be delayed; whether Athira’s trials are sufficiently powered to meet the planned endpoints; 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 drug 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; the impact of expanded drug candidate 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.

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