Athira Pharma to Present Results from Phase 2/3 LIFT-AD Clinical Trial of Fosgonimeton at the Clinical Trials on Alzheimer's Disease (CTAD) 2024 Meeting

October 22, 2024

BOTHELL, Wash., Oct. 22, 2024 (GLOBE NEWSWIRE) -- **Athira Pharma, Inc.** (NASDAQ: ATHA), a clinical stage biopharmaceutical company focused on developing small molecules to restore neuronal health and slow neurodegeneration, today announced that results from the Phase 2/3 LIFT-AD clinical trial of fosgonimeton to treat Alzheimer's disease (AD) will be presented at the 17 th Annual Clinical Trials on Alzheimer's Disease (CTAD) taking place October 29 - November 1, 2024, in Madrid, Spain.

Presentation Details:

Title: Fosgonimeton for the Treatment of Alzheimer's Disease; Efficacy and Safety Results from the LIFT-AD Trial
Session: Oral Communications: OC2
Date/Time: Tuesday, October 29 at 5:10 p.m., CET
Presenter: Anton P. Porsteinsson, M.D., Director of the University of Rochester Alzheimer's Disease Care, Research, and Education Program (AD-CARE) and a LIFT-AD investigator

As previously reported, topline results from the LIFT-AD trial did not achieve statistical significance for the primary endpoint of the Global Statistical Test (GST) nor its key secondary endpoints compared with placebo at 26 weeks. However, both components of GST, cognition (ADAS-Cog11) and function (ADCS-ADL23), directionally favored fosgonimeton treatment, and in pre-specified subgroups characterized by more rapid disease progression (moderate AD and APOE4 carriers), cognition and function improved or stabilized in the fosgonimeton treated group. In addition, data across biomarkers of protein pathology (Aβ42/40, p-Tau181, and p-Tau217), inflammation (GFAP) and neurodegeneration (NfL) showed directional changes in favor of fosgonimeton treatment that are consistent with the broad neuroprotective mechanism of HGF modulation.

"We believe the totality of the data supports the potential of HGF modulation for the treatment of neurodegenerative diseases," said Javier San Martin, M.D., Chief Medical Officer of Athira.

Athira is focused on advancing the clinical development program for ATH-1105, a novel, oral, next-generation small molecule positive modulator of the neurotrophic hepatocyte growth factor (HGF) system, as a potential treatment for neurodegenerative diseases, including amyotrophic lateral sclerosis (ALS) and Alzheimer's disease (AD). Athira is conducting a first-in-human Phase 1 (NCT 06432647) double-blind, placebo-controlled trial that is enrolling up to 80 healthy volunteers. The study is evaluating the safety and tolerability of ATH-1105 and includes measurements of pharmacokinetic outcomes. Athira completed the first cohort of healthy volunteers in June 2024 and expects to complete the full study by year-end 2024, with a goal to begin dosing ALS patients in 2025.

About Athira Pharma, Inc.
Athira Pharma, Inc., headquartered in the Seattle, Washington area, is a 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 drug 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: Athira's drug candidates as potential treatments for Alzheimer's disease, amyotrophic lateral sclerosis, and other neurodegenerative diseases; future development plans; the anticipated timing of its ongoing clinical trials and planned clinical trials; the potential learnings from preclinical studies and other nonclinical data, the LIFT-AD trial, and the ongoing Phase 1 trial of ATH-1105 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 regarding the safety and tolerability of ATH-1105; Athira's ability to advance its drug candidates into later stages of development; Athira's planned focus on the development of ATH-1105 for the treatment of amyotrophic lateral sclerosis; the ability to advance product candidates into later stages of development; and other information that is not historical information. 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," "target" 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; 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 new or changing laws and regulations; Athira may be unable to enter into new partnerships, financings or collaborations; 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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