Athira Pharma Completes First Cohort in Phase 1 Clinical Trial of ATH-1105, an Oral, Small Molecule Drug Candidate for Amyotrophic Lateral Sclerosis (ALS)

June 11, 2024

First-in-human, dose escalation study to evaluate safety, tolerability and pharmacokinetics in healthy volunteers with trial completion expected by year-end 2024

BOTHELL, Wash., June 11, 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 that it has completed the first cohort of healthy volunteers in its ongoing, first-in-human, dose escalation Phase 1 clinical study evaluating ATH-1105, an oral, small molecule positive modulator of the neurotrophic hepatocyte growth factor (HGF) system in development for the treatment of amyotrophic lateral sclerosis (ALS).

“We are particularly excited about the potential for ATH-1105 as a treatment for ALS based on our compelling preclinical data that have shown ATH-1105 can improve motor function, preserve nerve health and structure, and prolong survival in a mouse model of ALS,” said Javier San Martin, M.D., Chief Medical Officer of Athira. “We look forward to continued development of this promising therapeutic candidate for people with ALS, who are in need of therapies that improve the course of disease.”

“We are pleased to start this Phase 1 clinical trial and we are eager to explore the potential of ATH-1105 in ALS patients, which we are targeting to initiate in 2025,” said Mark Litton, Ph.D., President and Chief Executive Officer of Athira. “Our robust preclinical data to date have demonstrated ATH-1105's neuroprotective effects including a consistent reduction in plasma neurofilament light chain (NfL) levels, an established biomarker of neurodegeneration in ALS. By modulating the neurotrophic HGF system, we believe we can prevent or slow the progressive decline of motor and nerve function, reduce inflammation, preserve body weight and extend survival for patients suffering with this devastating neurodegenerative condition that has few treatment options.”

The Phase 1 (NCT 06432647) double-blind, placebo-controlled trial will enroll up to 80 healthy volunteers and evaluate single and multiple oral ascending doses. The study will evaluate the safety and tolerability of ATH-1105 and will include measurement of pharmacokinetic outcomes. Completion is expected by year-end 2024.

About ATH-1105
ATH-1105 is a next-generation, orally administered, small molecule drug candidate in development for the potential treatment of ALS. In preclinical models of ALS, ATH-1105 has been shown to significantly increase survival, enhance motor and nerve function, reduce peripheral nerve demyelination and axon degeneration, and improve neurodegeneration and inflammation.

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 expected to report topline data in the second half 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 a potential treatment for amyotrophic lateral sclerosis, Alzheimer’s disease, 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; 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.

Investor Contacts:
Julie Rathbun
Athira Pharma
Julie.rathbun@athira.com
206-769-9219