Athira Pharma to Present Data from First-in-Human Phase 1 Clinical Trial of ATH-1105 at the 4th Annual ALS Drug Development Summit

May 13, 2025

Data from Phase 1 clinical trial of ATH-1105 in healthy volunteers showed a favorable safety and tolerability profile; dose proportional pharmacokinetics and CNS penetration support continued clinical development

On-track to enable initiation of a clinical trial in ALS patients in late 2025

BOTHELL, Wash., May 13, 2025 (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 the Company will present data from a Phase 1 clinical trial of ATH-1105 in healthy volunteers at the 4th Annual ALS drug Development Summit taking place from May 12-14, 2025 in Boston, Massachusetts.

ATH-1105 is the Company's novel, orally available, brain-penetrant, next-generation small molecule drug candidate designed to positively modulate the neurotrophic HGF system for the potential treatment of neurodegenerative diseases, including amyotrophic lateral sclerosis (ALS).

"We are very encouraged by these first-in-human safety and pharmacokinetic data and how they reinforce ATH-1105's continued development as a potential treatment for ALS," noted Javier San Martin, M.D., Chief Medical Officer at Athira. "We look forward to enabling the initiation of a clinical trial in ALS patients in late 2025 and to evaluating ATH-1105's effect on an ALS validated biomarker (NfL)."

The data will be highlighted in an oral presentation titled, "Advancing ATH-1105 for ALS Through Early Clinical and PK Data," on Tuesday, May 13, 2025, at 11 am ET and a poster presentation titled, "ATH-1105 Enhances Motor Neuron Survival and Reduces TDP-43 Pathology in Preclinical ALS Models," on Tuesday, May 13, 2025, at 3 p.m. ET. The data, to be presented by Sherif Reda, Ph.D., Director, Discovery Research at Athira Pharma, and Kai-Bin Ooi, Director, Drug Development and Operations at Athira Pharma, will feature preclinical and Phase 1 data supporting the continued clinical development of ATH-1105 in ALS.

Key Highlights from the Presentation

- ATH-1105 has demonstrated consistent and robust beneficial effects in preclinical models of ALS
- ATH-1105 showed a favorable safety profile and was well tolerated in both single and multiple ascending dose studies in healthy volunteers
- ATH-1105 showed dose proportional pharmacokinetics and central nervous system (CNS) penetration

ATH-1105's potential is supported by a growing body of preclinical evidence demonstrating statistically significant improvements in nerve and motor function, biomarkers of inflammation and neurodegeneration, and survival in various models of ALS. These data have been presented at a variety of key scientific and medical meetings including the American Association of Neurology (AAN), the Alzheimer's Association International Congress (AAIC), the Northeast Amyotrophic Lateral Sclerosis Consortium® (NEALS), and the Motor Neurone Disease Association (MNDA), and published in Frontiers in Neuroscience, 2024.

About the Phase 1 Clinical Trial
The first-in-human Phase 1 (NCT 06432647) double-blind, placebo-controlled clinical trial enrolled 80 healthy volunteers to evaluate single and multiple oral ascending doses of ATH-1105. The trial was completed in November 2024 and evaluated the safety and tolerability of ATH-1105 and included measurements of pharmacokinetic outcomes. The results of the Phase 1 trial showed that ATH-1105 demonstrated a favorable safety profile and was well-tolerated in healthy volunteers, supporting continued clinical development.

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 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 amyotrophic lateral sclerosis and other neurodegenerative diseases; future development plans and the timing thereof; the potential learnings from preclinical studies and other nonclinical data and from our Phase 1 ATH-1105 clinical trial and their ability to inform future clinical development plans; expectations and timing regarding the initiation of a clinical trial of ATH-1105 in ALS patients; 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," "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; 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 may in the future be instituted against Athira, its directors and officers; possible negative interactions of Athira's drug candidates with other treatments; FDA regulatory delays and uncertainty and new policies implemented under the current administration, including executive orders, changes in the leadership of federal agencies such as the FDA and SEC, staff layoffs, budget cuts to agency programs and research, and changes in drug pricing controls; 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, including as a result of tariffs; the impact of competition; the impact of drug candidate development and clinical activities on operating expenses; the impact of new or changing laws and regulations; risks related to Athira's exploration of strategic alternatives; 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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