Athira Pharma Announces Encouraging Results from SHAPE Phase 2 Clinical Trial of Fosgonimeton for the Treatment of Parkinson's Disease Dementia and Dementia with Lewy Bodies

December 12, 2023

Exploratory findings add to increasing body of clinical and preclinical data supporting positive modulation of the neurotrophic HGF system as a potential therapeutic approach for neurodegenerative diseases

Cognitive measures in the 40 mg dose group bolster confidence in ongoing Phase 2/3 LIFT-AD clinical trial of fosgonimeton in Alzheimer's disease, which is on track to complete enrollment in early 2024 and report topline results in second half of 2024

BOTHELL, Wash., Dec. 12, 2023 (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 findings from the exploratory SHAPE Phase 2 clinical trial to evaluate fosgonimeton (ATH-1017) in patients with Parkinson's disease dementia and dementia with Lewy Bodies.

Fosgonimeton is a potentially first-in-class, investigational, small molecule designed to positively modulate the hepatocyte growth factor (HGF) system, which can activate neuroprotective, neurotrophic and anti-inflammatory pathways in the central nervous system.

"In this small exploratory trial, once daily treatment with fosgonimeton 40 mg showed positive effects in cognitive measures compared to placebo, with an observed statistically significant difference in ADAS-Cog13, and numeric positive differences in MMSE and COWAT over the 6-month double-blind treatment period," said Hans Moebius, M.D., Ph.D., Chief Medical Officer of Athira. "These findings support the potential of targeting HGF system positive modulation as a broadly applicable strategy for treating neurodegenerative diseases."

Kevin Church, Ph.D., Chief Scientific Officer of Athira, commented, "The findings from the cognitive measures in the SHAPE trial add to the data we have generated from preclinical models of dementia. Collectively, these preclinical and clinical outcomes support continued development of our HGF system positive modulators in diseases with differing pathologies."

The primary endpoint of SHAPE, a composite score of the change in Event-Related-Potential (ERP) P300 latency and cognitive assessment (ADAS-Cog13), was not met compared with placebo. However, all five patients in the modified intent to treat (mITT) population treated with fosgonimeton 40 mg once daily saw improvement in ADAS-Cog13 individually and collectively showed a statistically significant improvement (-7.2 points at 26 weeks) compared with placebo (n=7 mITT, p=0.0321). In addition, directional improvements in other cognitive, functional and biomarker measurements were observed in the fosgonimeton 40 mg treatment group. Results for patients in the 70 mg treatment group were inconsistent, potentially due, in part, to a higher dropout rate (50%) from baseline enrollment than both the 40 mg (22%) and placebo (22%) groups.

Fosgonimeton was generally well tolerated, with a favorable safety profile. There were no treatment-related serious adverse events or deaths observed in the study. The most common adverse event in the treatment groups was injection site reactions.

"These encouraging findings from the SHAPE trial further bolster our confidence in the ongoing Phase 2/3 LIFT-AD trial of fosgonimeton as a potential treatment for Alzheimer's disease and support our May 2023 amendment to the LIFT-AD protocol to pursue the 40 mg dose versus placebo and discontinue the 70 mg dose. We expect to complete enrollment of the LIFT-AD trial early in 2024 and to report topline results in the second half of 2024," said Mark Litton, Ph.D., President and Chief Executive Officer of Athira. "More broadly, we are encouraged by the clinical and preclinical evidence that support the potential therapeutic effects of HGF system positive modulation across a wide range of neurodegenerative diseases."

About SHAPE (NCT04831281)
SHAPE was a randomized, double-blind, placebo-controlled, parallel-group Phase 2 trial for ATH-1017 in subjects with Parkinson's disease dementia or Dementia with Lewy bodies. The SHAPE trial was originally designed to enroll approximately 75 individuals, but Athira elected to end enrollment in October 2022 at 28 subjects due to subsequently identified study design limitations and a prioritization of resources toward the LIFT-AD trial in Alzheimer's disease. Study participants were randomized across two dose groups and one placebo group on a 1:1:1 basis to receive a subcutaneous injection of ATH-1017 or placebo once daily over a treatment course of 26 weeks. 29% of participants were on background therapy with acetylcholinesterase inhibitors (AChEIs). The primary endpoint for SHAPE was change in Event-Related-Potential (ERP) P300 latency, a functional measure of working memory processing speed, and the composite Global Statistical Test, which is an unbiased mathematical algorithm that combines the scores from the cognitive assessment.

SHAPE results are expected to be presented at an upcoming medical conference.

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 targeting the neurotrophic HGF system for Alzheimer's and Parkinson's disease, Dementia with Lewy bodies, and amyotrophic lateral sclerosis. 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: product candidates as a potential treatment for Alzheimer's disease, Parkinson's disease, Parkinson's

disease dementia, Dementia with Lewy bodies, and other neurodegenerative diseases, such as amyotrophic lateral sclerosis; future development plans; the anticipated reporting of data; the potential learnings from the SHAPE trial and their ability to inform and improve future clinical development plans; expectations regarding the potential efficacy and commercial potential of Athira's product candidates; 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," "suggest," "potential," 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 from preclinical and clinical trials may not support the safety, efficacy and tolerability of Athira's product candidates; development of product candidates may cease or be delayed; regulatory authorities could object to protocols, amendments and other submissions; future potential regulatory milestones for product 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 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 pandemics or health epidemics, 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 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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