Athira Pharma Presents Clinical and Preclinical Data Supporting Therapeutic Potential of Fosgonimeton in Alzheimer's and Parkinson's Diseases at AD/PD™ 2024 International Conference

March 8, 2024

Data adds to increasing body of evidence supporting positive modulation of the neurotrophic HGF system as a potential therapeutic approach for neurodegenerative diseases such as Parkinson's disease, Alzheimer's disease, and dementia with Lewy bodies

Results from exploratory SHAPE Phase 2 trial show encouraging safety and pro-cognitive measures with fosgonimeton treatment and underscore confidence in Phase 2/3 LIFT-AD trial with data anticipated in the second half of 2024

BOTHELL, Wash., March 08, 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, presented new clinical and preclinical data further highlighting the therapeutic potential of fosgonimeton at the AD/PD™ 2024 International Conference on Alzheimer's and Parkinson's Diseases and Related Neurological Disorders, being held in Lisbon, Portugal March 5 – 9, 2024.

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.

"Data presented at AD/PD, in tandem with the existing body of preclinical and clinical evidence, continue to support the potential of targeting the neurotrophic HGF system to treat neurodegenerative diseases, including Parkinson's disease, Alzheimer's disease and dementia with Lewy bodies," said Mark Litton, Ph.D., President and Chief Executive Officer of Athira. "We believe safety and efficacy outcomes from the exploratory SHAPE Phase 2 clinical trial presented at this year's AD/PD, along with previous clinical data, support the continued development of fosgonimeton. The encouraging pro-cognitive effects observed in the 40 mg dose group, assessed for fosgonimeton for the first time in Parkinson's disease dementia and dementia with Lewy bodies, underscore our confidence in the Phase 2/3 LIFT-AD trial, which is evaluating fosgonimeton at 40 mg as a potential treatment for mild-to-moderate Alzheimer's disease, with data expected in the second half of 2024."

Athira presented an expanded dataset from the exploratory SHAPE Phase 2 clinical trial evaluating fosgonimeton in Parkinson's disease dementia and dementia with Lewy bodies as a follow up from data shared in December 2023. While the primary endpoint was not met by protocoled analysis compared with placebo, as previously disclosed, the data indicated a favorable safety and tolerability profile for fosgonimeton in trial participants. In addition, changes in ADAS-Cog13 observed in the fosgonimeton 40 mg dose arm were suggestive of a pro-cognitive effect, which was assessed for fosgonimeton for the first time in these disease states. These findings support the potential therapeutic benefit of modulating the neurotrophic HGF system with fosgonimeton for neurodegenerative diseases.

"We're pleased to be presenting additional preclinical data highlighting the neuroprotective effects of fosgonimeton in models of both Alzheimer's and Parkinson's diseases at AD/PD 2024," said Kevin Church, Ph.D., Chief Scientific Officer of Athira. "In Alzheimer's disease models, key results showed that the neuroprotective effects of fosgonimeton against glutamate toxicity in vitro are driven, in part, by activation of pro-survival signaling pathways that may help to counteract neurodegenerative hallmarks such as tau pathology and mitochondrial dysfunction."

Dr. Church continued, "In models of Parkinson's, the dataset highlights the ability of fosgonimeton to mitigate pathological alterations associated with α-synuclein toxicity in vitro and in vivo. In an aged mouse model of Parkinson's that included α-synuclein pathology and GBA1 inhibition, fosgonimeton improved motor function, promoted dopaminergic neuron survival, and reduced α-synuclein aggregation. This continued research of fosgonimeton adds to the body of evidence that positive modulation of the neurotrophic HGF system is a potential therapeutic approach for Parkinson's and other neurodegenerative diseases."

Presentation Details

Title: Results from SHAPE: A Phase 2 Study of Fosgonimeton in Patients with Parkinson's Disease Dementia and Dementia with Lewy Bodies
Abstract Number and Board Number: #1857; #0465
Date/Time: Wednesday, March 6, 9:00 a.m. WET – Thursday, March 7, 6:00 p.m. WET
Presenter: Hans Moebius, M.D., Ph.D., Senior Scientific Advisor, Athira Pharma

Title: Neuroprotective Mechanisms of Fosgonimeton Against Excitotoxicity in Primary Neuron Culture
Abstract Number and Board Number: #1757; #0209
Date/Time: Friday, March 8, 9:00 a.m. WET – Saturday, March 9, 6:00 p.m. WET
Presenter: Sherif Reda, Ph.D., Associate Director, Discovery Biology, Athira Pharma

Title: Fosgonimeton protects against α-synuclein-mediated pathology in preclinical models of Parkinson's disease
Abstract Number and Board Number: #1243; #0546
Date/Time: Friday, March 8, 9:00 a.m. WET – Saturday, March 9, 6:00 p.m. WET
Presenter: Sharay Setti, Ph.D., Senior Scientist II, Athira Pharma

The presentations are available on the Scientific Publications & Presentations page of the company's website at www.athira.com.

About Fosgonimeton
Fosgonimeton is a small molecule designed to enhance the activity of the neurotrophic hepatocyte growth factor signaling system, an endogenous repair mechanism for a healthy nervous system. The function of the neurotrophic HGF system may be impaired in conditions of neurodegeneration.

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 SHAPE (NCT04831281)
SHAPE was a randomized, double-blind, placebo-controlled, parallel-group Phase 2 trial for ATH-1017 (fosgonimeton) 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 mild-to-moderate 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 (fosgonimeton) or placebo once daily over a treatment course of 26 weeks. The primary endpoint for SHAPE was a composite score of the change in Event-Related-Potential (ERP) P300 latency and cognition (ADAS-Cog13), which was not met by protocoled analysis.

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: 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; future development plans; the anticipated reporting of data; 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 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 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 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; 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.

Investor & Media Contact:

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