Athira Pharma Presents Preclinical Data Demonstrating New Insights into the Mechanism by Which Fosgonimeton Protects Neurons from Alzheimer's Disease-Related Pathology at the Alzheimer's Association International Conference (AAIC) 2024

July 31, 2024

Fosgonimeton mitigated amyloid-β-induced toxicity, lowered pTau levels and reduced disruption of protein clearance mechanisms that may contribute to pTau pathology

Fosgonimeton treatment, alone and in combination with lecanemab, protected cultures of primary neurons from the toxic effects of amyloid-β

BOTHELL, Wash., July 31, 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 preclinical data further highlighting the therapeutic potential of fosgonimeton at the Alzheimer's Association International Conference (AAIC) 2024, being held in Philadelphia from July 28-Aug. 1, 2024.

"We are pleased to be presenting new preclinical data at AAIC 2024 that further demonstrate the broad neuroprotective activity of fosgonimeton and its effects on Alzheimer's disease-related protein pathology," said Kevin Church, Ph.D., Chief Scientific Officer of Athira. "Previous preclinical studies have shown that fosgonimeton protects neurons through several mechanisms, including reducing inflammation, improving mitochondrial function, activating prosurvival signaling pathways, and reducing levels of pTau. Here, we described potential mechanisms as to how fosgonimeton treatment may impact levels of key pathological proteins in Alzheimer's disease models. We also demonstrated that the neuroprotective ability of fosgonimeton against amyloid-*β*-induced toxicity in primary neurons is maintained in the presence of lecanemab, and, in some conditions, the combination of fosgonimeton and lecanemab led to numerically higher levels of neuroprotection"

"These preclinical data are compelling as they showed fosgonimeton attenuated amyloid-β-induced autophagic impairments in primary cortical neurons, which may have important implications regarding the attenuation of pTau pathology in Alzheimer's disease," stated Mark Litton, Ph.D., President and Chief Executive Officer of Athira. "Preclinical data such as these support our novel approach to targeting the neurotrophic HGF system as a potential treatment for Alzheimer's disease and add more insights into the pleotropic effect of fosgonimeton in Alzheimer's disease pathology. We look forward to potentially demonstrating how enhancing this system may translate into clinical benefit."

AAIC 2024 Presentation Details

Title: Fosgonimeton attenuates amyloid-β-induced autophagic impairments in primary cortical neurons
Poster: #49
Date/Time: Wednesday, July 31, 8:00 a.m. ET – 4:15 p.m. ET
Presenter: Sherif Reda, Ph.D., Associate Director, Discovery Biology, Athira Pharma

Highlights of this presentation show that:

- Fosgonimeton can mitigate amyloid-β-induced disruption of autophagy, an essential cellular process that plays a key role in the removal of pathological proteins, such as pTau, and is known to be impaired in Alzheimer's disease.
- Improvement in autophagy may partly explain the reduction in pTau observed in these models and suggest that fosgonimeton may have beneficial impacts on key indicators of protein pathology, and the associated neurodegeneration in Alzheimer's disease.

Title: Neuroprotective effects of fosgonimeton and amyloid-β-targeting monoclonal antibodies against amyloid-β toxicity in primary neuron culture
Poster: #50
Date/Time: Wednesday, July 31, 8:00 a.m. ET – 4:15 p.m. ET
Presenter: Robert W. Taylor, PhD, Director, Discovery Biology, Athira Pharma

Highlights of this presentation show that:

- Fosgonimeton is neuroprotective against amyloid-beta-mediated toxicity in primary neurons, either alone or in combination with lecanemab, and, in some conditions, the combination of fosgonimeton and lecanemab led to numerically higher levels of neuroprotection.
- The data support the continued investigation of fosgonimeton and Aβ-mAbs as a potential combination therapy for the treatment of Alzheimer's disease.

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

About Fosgonimeton
Fosgonimeton is a potentially first-in-class, once daily, subcutaneously administered small molecule drug candidate. 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 the Phase 2/3 LIFT-AD Clinical Trial
The Phase 2/3 LIFT-AD clinical trial is a randomized, double-blind, placebo-controlled clinical trial evaluating once-daily subcutaneous injections of fosgonimeton 40 mg compared to placebo in people with mild-to-moderate Alzheimer's disease. Topline results from the trial, which enrolled approximately 315 patients, is targeted by the end of the third quarter of 2024. The primary endpoint of LIFT-AD is the Global Statistical Test (GST), a combination of the results from the co-key secondary endpoints ADAS-Cog11 and ADCS-ADL23, measurements of cognition and function, respectively. Additional key secondary and exploratory endpoints include changes in plasma biomarkers of neurodegeneration, protein pathology, and neuroinflammation. Additional information about the LIFT-AD study can be found at: NCT04488419.

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 targeted to report topline data by the end of the third quarter 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 potential treatments for Alzheimer's disease, Parkinson's disease, dementia with Lewy bodies, 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," "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; the anticipated timing of the topline data from the LIFT-AD trial may be delayed; 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 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.

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