# Athira Pharma Highlights Therapeutic Potential of Fosgonimeton in Presentation of Additional Biomarker Data in Mild-to-Moderate Alzheimer's Disease Patients from ACT-AD Phase 2 Study at CTAD Conference

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*Fosgonimeton treatment-related reductions in biomarkers of neurodegeneration (NfL) and neuroinflammation (GFAP) significantly correlated with improvements in clinical outcomes as assessed by the GST, a composite score of cognition (ADAS-Cog11) and function (ADCS-ADL23)*

*Data demonstrate fosgonimeton treatment significantly improved NfL, a biomarker of neurodegeneration and showed directional improvements in biomarkers of neuroinflammation (GFAP, YKL-40) and Alzheimer's protein pathologies (A β 42/40 ratio, p-Tau181) compared with placebo among patients not taking acetylcholinerase inhibitors*

*Totality of data suggests fosgonimeton's potential as a neuroprotective, potentially disease-modifying, therapy for mild-to-moderate Alzheimer's disease*

BOTHELL, Wash., Nov. 29, 2022 (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 the presentation of additional biomarker data from the completed, exploratory ACT-AD Phase 2 study of fosgonimeton (ATH-1017) in patients with mild-to-moderate Alzheimer's disease (AD) at the 15th Clinical Trials on Alzheimer's Disease (CTAD) conference.

The late-breaking poster presentation highlights the effect of fosgonimeton treatment on biomarkers associated with neurodegeneration (NfL), neuroinflammation (GFAP, YKL-40), and Alzheimer's specific protein pathologies (Aβ 42/40 ratio and p-Tau181).

"These additional biomarker data provide further support of the therapeutic potential of fosgonimeton in patients with mild-to-moderate Alzheimer's disease," said Hans J. Moebius, M.D., Ph.D., Chief Medical Officer of Athira Pharma. "Our analyses of the completed, exploratory ACT-AD study found that among patients not on concomitant acetylcholinerase inhibitors, fosgonimeton treatment improved levels of serum biomarkers known to be associated with neurodegeneration and neuroinflammation. Furthermore, directional improvements in key biomarkers associated with Alzheimer's disease pathology, Aβ 42/40 ratio and p-Tau181, provide evidence supporting fosgonimeton's potential as a disease-modifying therapy."

"Notably, in the context of clinical outcomes, these biomarker data showed that fosgonimeton treatment-related reductions in NfL and GFAP significantly correlate with improvements in the GST, a composite score of cognition and function," added Dr. Moebius.

Key findings from the presentation include:

- Baseline NfL (neurodegeneration) levels may predict functional decline in patients with mild-to-moderate AD as assessed by the change from baseline measures of ADCS-ADL23.
- Fosgonimeton treatment significantly reduced levels of NfL (neurodegeneration, p=0.0241) and numerically reduced levels of GFAP and YKL-40 (neuroinflammation).
- Fosgonimeton treatment showed directional improvements in biomarkers of AD-associated protein pathologies (Aβ 42/40 ratio and p-Tau181) compared to placebo.
- Fosgonimeton treatment-related reductions in NfL and GFAP significantly correlated with improvements in clinical outcomes, as assessed by the Global Statistical Test (GST), a composite score of ADAS-Cog11 and ADCS-ADL23.

"These compelling biomarker data provide further evidence that supports the ongoing development of fosgonimeton and our pipeline of HGF/MET-modulating compounds," said Mark Litton, Ph.D., Chief Executive Officer of Athira Pharma. "Our clinical and preclinical data continue to support the potential neuroprotective and disease-modifying properties of enhancing the HGF/MET neurotrophic system. We are excited by our progress with the ongoing Phase 2/3 LIFT-AD clinical study of fosgonimeton in this same patient population and look forward to completing enrollment of this potentially pivotal study in mid-2023 with topline data in early 2024."

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

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**About Fosgonimeton**
Fosgonimeton is a small molecule designed to enhance the activity of hepatocyte growth factor (HGF) and its receptor, MET, to impact neurodegeneration and regenerate brain tissue. The function of the HGF/MET receptor system may be impaired in the brain under conditions of neurodegeneration. In addition to Alzheimer's disease, fosgonimeton has the potential to address the broader dementia population, including Parkinson's disease dementia and Dementia with Lewy bodies, as the mode of action focuses on network recovery and synaptic signal transmission in the brain.

**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 provide rapid cognitive improvement and alter the course of neurological diseases with its novel mechanism of action. Athira is currently advancing its pipeline of therapeutic candidates targeting the HGF/MET neurotrophic system for Alzheimer's and Parkinson's disease dementia, Dementia with Lewy bodies and neuropsychiatric indications. For more information, visit www.athira.com. You can also follow Athira on Facebook, LinkedIn and @athirapharma on 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 fosgonimeton as a potential treatment for Alzheimer's disease, Parkinson's disease dementia, Dementia with Lewy bodies, and other dementias, neuropathy and neuropsychiatric indications; Athira's platform technology and potential therapies; future development plans; clinical and regulatory objectives and the timing thereof; 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," "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 for our product candidates from our preclinical and clinical trials will not support the safety, efficacy and tolerability of our product candidates; cessation or delay of any of the ongoing clinical trials and/or Athira's development of fosgonimeton and other product candidates may occur; future potential regulatory milestones of fosgonimeton and other product candidates, including those related to current and planned clinical studies may be insufficient to support regulatory submissions or approval; the impact of the COVID-19 pandemic on Athira's business, research and clinical development plans and timelines, and the regulatory process for Athira product candidates; 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 us and certain of our directors and officers; clinical trials may not demonstrate safety and efficacy of any of Athira's product candidates; 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 the COVID-19 pandemic, 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. 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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