Athira Pharma Announces Publication of Phase 1 Results for Fosgonimeton (ATH-1017) in The Journal of Alzheimer's Disease

February 22, 2022

Fosgonimeton demonstrated a statistically significant improvement of Event-Related Potential (ERP) P300 latency as compared with placebo in Alzheimer's disease patients

Fosgonimeton was well-tolerated across all dose levels and showed dose-proportional pharmacokinetics and encouraging pharmacodynamic activity

Announces fosgonimeton as World Health Organization's recommended international nonproprietary name for ATH-1017

BOTHELL, Wash., Feb. 22, 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 peer-reviewed publication of data from a Phase 1 clinical trial of fosgonimeton (ATH-1017) in *The Journal of Alzheimer's Disease*.

The article, titled "Safety, tolerability, pharmacokinetics and pharmacodynamics of the positive modulator of HGF/MET, fosgonimeton, in healthy volunteers and subjects with Alzheimer's disease: randomized, placebo-controlled, double-blind, Phase 1 clinical trial," and includes results demonstrating that fosgonimeton showed a positive safety and tolerability profile across all dose levels tested and dose-proportional pharmacokinetics and encouraging pharmacodynamic activity.

"These encouraging results showed a positive safety and tolerability profile of fosgonimeton across a wide dose range, and the pharmacodynamics support blood brain barrier penetration. Importantly, we believe the significant reduction of ERP P300 latency levels seen in the Alzheimer's disease patient cohort on active treatment may be suggestive of enhanced synaptic function and, ultimately, the potential procognitive properties of fosgonimeton," said Hans Moebius, MD, PhD, Chief Medical Officer of Athira. "These data support our ongoing Phase 2 ACT-AD and Phase 3 LIFT-AD trials evaluating fosgonimeton's potential as a treatment for Alzheimer's disease. We look forward to sharing the Phase 2 ACT-AD top-line data in the second quarter of 2022."

About the Phase 1 Trial

The randomized, placebo-controlled, double-blind Phase 1 clinical trial of fosgonimeton enrolled a total of 88 subjects. This includes 48 healthy young male volunteers in a single ascending dose cohort; 29 healthy elderly volunteers in a multiple ascending dose cohort; and 11 Alzheimer's patients in a fixed-dose cohort. All participants received fosgonimeton or placebo by daily subcutaneous injection. Of those randomized to fosgonimeton, the healthy single ascending dose cohort received doses ranging from 2 mg to 90 mg, the multiple ascending dose cohorts received daily doses ranging from 20 mg to 80 mg, while the Alzheimer's cohort received daily doses of 40 mg. Neurophysiological signals were measured using quantitative electroencephalogram (qEEG) and event-related potential (ERP) P300 latency to assess brain penetration and target engagement as well as working memory processing speed.

Fosgonimeton showed a positive safety and tolerability profile across all doses tested in all cohorts. Fosgonimeton demonstrated fast-onset and sustained gamma power induction effect on qEEG. Additionally, results in Alzheimer's patients demonstrated a statistically significant effect toward ERP P300 latency normalization as compared with placebo (p=0.027; n=7 at 40 mg fosgonimeton vs. n=4 placebo). The complete study results can be accessed here.

Athira also announced that the World Health Organization's (WHO) International Nonproprietary Names (INN) Expert Committee has recommended fosgonimeton (foz-go-nih-MEH-ton) as the nonproprietary name for ATH-1017, the company's lead small molecule targeting HGF/MET. In recommending the name, WHO designated the suffix stem "-meton" as a novel drug class based on targeted positive modulation of HGF/MET.

About Fosgonimeton (ATH-1017)

Fosgonimeton (ATH-1017) 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.

Athira is currently evaluating fosgonimeton in multiple clinical trials:

- ACT-AD, a Phase 2 Study in mild-to-moderate Alzheimer's disease (NCT04491006), which completed enrollment in October 2021;
- LIFT-AD, a Phase 3 Study in mild-to-moderate Alzheimer's disease (NCT04488419), which is currently recruiting;
- An Open Label Extension trial in mild-to-moderate Alzheimer's disease (NCT04886063), which is currently enrolling; and

- SHAPE, a Phase 2 clinical trial in participants with Parkinson's disease dementia or Dementia with Lewy bodies (NCT04831281), which is currently recruiting.

The ACT-AD trial is supported by a grant from the National Institute on Aging of the National Institutes of Health under Award Number R01AG06268. The information presented in this press release is solely the responsibility of Athira and does not necessarily represent the official views of the National Institutes of Health.

About Athira Pharma, Inc.
Athira Pharma, Inc., headquartered in the Seattle 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 lead candidate, fosgonimeton, a novel small molecule for Alzheimer's, Parkinson's disease dementia and Dementia with Lewy bodies. 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 release 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 and Dementia with Lewy bodies, and other dementias; 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; the anticipated reporting of data; 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," "would," "expect," "plan," "believe," "intend," "pursue," "continue," 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 preliminary data for Athira's fosgonimeton product candidate from the Phase 1a/b trials will not continue or persist in current or planned clinical trials; cessation or delay of any of the ongoing clinical trials and/or Athira's development of fosgonimeton and other product candidates may occur; 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; the outcome of legal proceedings which 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; Athira's assumptions regarding the sufficiency of its cash, cash equivalents and investments to fund its planned operations may be incorrect; while P300 latency is a functional measure that is highly correlated with cognition, Athira may not successfully establish a connection between these P300 latency results and improved cognition; 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.

Investor & Media Contact:
Julie Rathbun
Julie.rathbun@athira.com
206-769-9219