Athira Pharma Presents Study Overview and Baseline Data from ACT-AD Phase 2 Trial of Fosgonimeton in Mild-to-Moderate Alzheimer's Disease at the 2022 AD/PD™ Congress

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BOTHELL, Wash., March 20, 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 that study overview and baseline data from ACT-AD, a fully enrolled Phase 2 clinical trial of Athira's lead development candidate, fosgonimeton (ATH-1017) in study participants with mild-to-moderate Alzheimer's disease (AD), were presented in an oral presentation at the International Conference on Alzheimer's and Parkinson's Disease and Related Neurological Diseases (AD/PD™ 2022) taking place in Barcelona, Spain, and virtually from March 15-20, 2022.

Of the 77 study participants enrolled in the randomized, double-blind, placebo-controlled trial, the mean age is 71.4 years, with 50.6% female and 49.4% male, and an average baseline MMSE of 19.3. This includes 31 patients with mild Alzheimer's disease (mean baseline MMSE 21.8) and 46 with moderate Alzheimer's disease (mean baseline MMSE 17.5). The average frequency of the APOe4 gene among all study participants is in line with the general AD population. The preliminary baseline ERP P300 latency is 381 milliseconds. At a preliminary data cut, 57 patients completed the study and approximately 14 percent discontinued prior to study completion.

"The baseline data demonstrate that the patient population enrolled in the ACT-AD study are representative of the mild-to-moderate Alzheimer's population and appropriate to evaluate the effectiveness of fosgonimeton on ERP P300 latency, a functional, objective measure of working memory processing speed," said Hans Moebius, M.D., Ph.D., Chief Medical Officer at Athira. "Change in ERP P300 latency may be indicative of enhanced synaptic function and potentially improving Alzheimer's disease. The topline data readout from ACT-AD, targeted for the second quarter of this year, will be informative for the future analysis of our currently enrolling, potentially pivotal Phase 3 LIFT-AD study, which has been conducted in parallel with ACT-AD."

The data slides presented during the AD/PD™ onsite session #113 are titled, "Study Design and Participant Characteristics of a Phase 2 trial of ATH-1017, a Novel Treatment for Mild-to-Moderate Alzheimer's Disease," and can be found on the Events and Presentations page of the Investors section of the company's website at www.athira.com.

About the ACT-AD Trial
ACT-AD is a randomized, double-blind, placebo-controlled, 26-week trial evaluating fosgonimeton for the treatment of mild-to-moderate AD. Eligible participants had to have a clinical diagnosis of probable AD dementia according to the NIA-AA criteria. Those enrolled, presented with mild-to-moderate AD dementia as demonstrated by a Mini-Mental State Exam (MMSE) score of 14 to 24 and a Clinical Dementia Rating (CDR) scale global score of 1 or 2. Study participants were randomized across two dose groups and the placebo group on a 1:1:1 basis to receive daily subcutaneous injection of fosgonimeton or placebo.

The primary endpoint of ACT-AD is the change in Event-Related-Potential (ERP) P300 Latency, a functional, objective measure of working memory processing speed. Secondary endpoints include measures of cognition (ADAS-COG11), the clinical global impression of change (ADCS CGIC), and the instrumental activities of daily living (ADCS-ADL23). Additionally, plasma pharmacokinetics of fosgonimeton will be assessed.

The ACT-AD trial completed enrollment in October 2021, with 77 participants. Topline data are anticipated in the second quarter of 2022. Upon completion of the ACT-AD double-blind period, eligible participants can enroll in an Open Label Extension study of fosgonimeton for up to an additional 26 weeks.

Athira's 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 and at the AD/PD Congress is solely the responsibility of Athira and does not necessarily represent the official views of the National Institutes of Health.

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.
In addition to ACT-AD, Athira is currently evaluating fosgonimeton in multiple clinical trials:

- 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.

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 therapeutic candidate, fosgonimeton, a novel small molecule for Alzheimer's and 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 1 Part A and 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.

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