Athira Pharma Announces Completion of Enrollment in Phase 2 ACT-AD Trial Evaluating ATH-1017 for Mild-to-Moderate Alzheimer's Disease

October 22, 2021

-Topline data targeted for 1H22-

BOTHELL, Wash., Oct. 22, 2021 (GLOBE NEWSWIRE) -- Athira Pharma, Inc. (NASDAQ: ATHA), a late clinical-stage biopharmaceutical company focused on developing small molecules to restore neuronal health and stop neurodegeneration, announced today that it has completed enrollment in ACT-AD, a Phase 2 randomized, placebo-controlled study of ATH-1017 in patients with mild-to-moderate Alzheimer's disease. ATH-1017 is a small molecule designed to enhance the activity of Hepatocyte Growth Factor (HGF) at its receptor, MET, which are expressed in the central nervous system to promote brain health and function. Athira expects to report topline results from the trial in the first half of 2022.

"The completion of enrollment in our ACT-AD trial is an important step forward in advancing ATH-1017 as a potential new treatment option for patients suffering from Alzheimer's and other dementias," said Mark Litton, Ph.D., M.B.A, President and Chief Executive Officer at Athira. "We look forward to building on this momentum and sharing topline results from this Phase 2 trial in the first half of 2022. As part of our overall clinical development program to maximize the full potential of ATH-1017, we plan to initiate a clinical trial in Parkinson's disease dementia later this year. At Athira, we are committed to improving the lives of patients and their caregivers, and we are proud of our progress towards this goal to date."

"The completion of enrollment in ACT-AD is an important clinical milestone for Athira. Results from this trial may provide Athira with supportive information that can help optimize our ongoing potentially pivotal LIFT-AD trial and confirm the statistically significant improvement in P300 latency, a functional measure of working memory processing speed, demonstrated in our early trial. We are thankful to have reached this milestone and for the combined efforts of our researchers, partners and the patient and caregiver community," said Hans Moebius, M.D., Ph.D., Chief Medical Officer at Athira. "The pathophysiology of Alzheimer's disease is complex and includes not only the hallmarks of beta-amyloid deposits and neurofibrillary tangles, but neuroinflammation, vascular dysfunction, and neurodegeneration. By focusing on neuronal network recovery, ATH-1017's novel mechanism of action is agnostic to the underlying disease pathology of Alzheimer's and other dementias."

The ACT-AD study (www.act-adtrial.com, NCT04491006) is a randomized, double-blind, placebo-controlled, 26-week Phase 2 clinical trial. Participants were randomized across two dose groups and one placebo group on a 1:1:1 basis to receive a daily subcutaneous injection of ATH-1017 or placebo over a treatment course of 26 weeks. The study has enrolled 77 patients with mild-to-moderate Alzheimer's disease across 14 sites in the United States and Australia. Patients will be evaluated for improvement in cognition, global, and functional assessments comparing treatment arms to placebo. ACT-AD will also use electroencephalogram (EEG), to measure quantitative electroencephalogram (qEEG), and Event-Related-Potential (ERP P300), a functional measure of working memory processing speed. Following completion of the 26-week treatment period during the LIFT-AD or ACT-AD trials, patients may elect to continue on the open label extension and receive treatment with ATH-1017 at the high dose (70 mg/day) for up to an additional 26 weeks.

About ATH-1017
ATH-1017, Athira's lead therapeutic candidate, is a positive modulator of HGF/MET. ATH-1017 is a prodrug that is administered via subcutaneous injection in its inactive form and rapidly converted in plasma to an active tyrosine metabolite (dihexa). Since 2018, ATH-1017 has been assessed in multiple preclinical and clinical studies by Athira and by its third-party contractors. Studies performed by third parties sponsored by Athira regarding ATH-1017's safety profile and treatment potential include the following:

- A non-clinical study in an Alzheimer's disease (AD) animal model (APP1/PS1), which showed that ATH-1017 treatment increased the qEEG gamma power that is associated with cognitive processing and memory.
- IND enabling studies including nonclinical GLP long-term toxicology and safety pharmacology studies performed by independent contract research organizations with validated methods and audited reports.
- A Phase 1a/b clinical trial in healthy young, healthy elderly, and AD subjects, in which ATH-1017 was shown to be well-tolerated with no serious adverse events and demonstrated statistically significant improvement in Event-Related Potential, or ERP. ERP P300 latency, an objective measure of working memory processing speed, was noted in patients with AD following multiple dose treatments with ATH-1017 compared with those receiving placebo ($P<0.05$). Recently, an independent auditing firm affirmed the GCP compliance and data management quality of the Phase 1a/b clinical trial.

About Athira Pharma, Inc.
Athira, headquartered in the Seattle area, is a late clinical-stage biopharmaceutical company focused on developing small molecules to restore neuronal health and stop neurodegeneration. Athira aims to provide rapid cognitive improvement and alter the course of neurological diseases with our novel mechanism of action. Athira is currently advancing its lead therapeutic candidate, ATH-1017, a novel small molecule for Alzheimer's and Parkinson's disease dementia. 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 ATH-1017 as a potential treatment for Alzheimer's disease and other dementias; Athira's platform technology and potential therapies; future development plans; clinical and regulatory objectives and the timing thereof, including the timing of the ACT-AD and LIFT-AD clinical trials and the timing of the Phase 2 clinical trial of ATH-1017 for treatment of Parkinson's disease dementia; 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," 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 ATH-1017 product candidate from the Phase 1a/b trials will not continue or persist; cessation or delay of any of the ongoing clinical trials and/or Athira's development of ATH-1017 and other product candidates may occur; future potential regulatory milestones of ATH-1017, 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 results of operations, including impact on Athira's clinical trial sites and contractors who act for or on Athira's behalf, may be more severe and more prolonged than currently anticipated; 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 research and development efforts and its ability to advance product candidates into later stages of development may fail; any one or more of Athira's product candidates may not be successfully developed, approved or commercialized; 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; 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 competition; the impact of new or changing laws and regulations; adverse conditions in the general domestic and global economic markets; 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
Athira Pharma
Julie.rathbun@athira.com
206-769-9219