Athira Pharma Announces Initiation of Open Label Extension Study for LIFT-AD and ACT-AD Clinical Trials of ATH-1017 for Alzheimer's Disease

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Study Extension allows for additional 26 weeks of treatment on ATH-1017

BOTHELL, Wash., July 06, 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, today announced that it is enrolling patients into an open label extension (OLEX) study for its ongoing Phase 2/3 LIFT-AD and Phase 2 ACT-AD studies of ATH-1017 for the treatment of mild-to-moderate Alzheimer's disease.

"This treatment extension allows us to meet investigator and patient interest in continuing treatment with ATH-1017. We can now collect up to 1 year of safety and efficacy data on ATH-1017, and patients who received placebo during the randomized portion of the trial will now be able to receive up to 26 weeks of therapy," said Hans Moebius, M.D., Ph.D., Chief Medical Officer at Athira. "It's rewarding to have our first patients completing six months of study now continue their treatment. Our novel treatment approach is agnostic to the underlying disease pathology and is designed to focus on neuronal regeneration, which has the potential to improve clinical outcomes for patients."

"There remains an urgent need for therapies that improve cognition for patients who are living with mild-to-moderate Alzheimer's disease," said Michael Mega, M.D., Ph.D., Director of the Center for Cognitive Health and a principal investigator in the ACT-AD trial. "The data we will continue to collect in this open label extension could help us to better understand the long-term safety and efficacy profile of ATH-1017 and could help Athira best design future clinical trials of ATH-1017."

The LIFT-AD and ACT-AD trials are evaluating ATH-1017, a small molecule therapeutic designed to enhance the activity of Hepatocyte Growth Factor (HGF) and its receptor, MET, which are expressed in the central nervous system, in order to promote brain health and function. The randomized, double-blind, placebo-controlled trials are evaluating the safety and efficacy of ATH-1017 in mild-to-moderate Alzheimer's disease. Patients are stratified 1:1:1 to receive low dose ATH-1017 (40 mg/day), high dose ATH-1017 (70 mg/day) or placebo.

Patients in both trials are being evaluated for improvement in cognition, global and functional assessments comparing treatment arms to placebo. In the ACT-AD trial, quantitative electroencephalograms (qEEG) are obtained, and Event-Related-Potentials (ERP P300), a functional measure of working memory processing speed and executive function is assessed. Topline data of ACT-AD are targeted for early 2022 and topline data from LIFT-AD are targeted by the end of 2022.

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. Investigators and patients will remain blinded to treatment group assignment in the original trials.

For more information on LIFT-AD or ACT-AD trials, visit www.lift-adtrial.com or www.act-adtrial.com. For more information on this open-label extension study, refer to NCT# NCT04886063 or visit athiraclinicaltrials.com/OLEX.

ATH-1017 Clinical Results
Athira's completed Phase 1a/b clinical trials of ATH-1017 for the treatment of Alzheimer's disease established that the treatment was generally well tolerated at all tested doses. Measures evaluating brain activity by electroencephalogram (qEEG) also produced a strong suite of translational data. Additionally, a statistically significant improvement in Event-Related Potential (ERP) P300 latency, a functional measure of working memory processing speed and executive function, was noted in patients with Alzheimer's disease following multiple dose treatments with ATH-1017 compared with those receiving placebo. Athira is seeking to confirm a connection between P300 latency improvement and clinical cognitive benefit by ATH-1017 treatment.

ATH-1017 Patent Allowance
Athira was granted U.S. Patent No. 11,021,514 by the U.S. Patent and Trademark Office on June 1, 2021, covering the composition of matter for ATH-1017. The patent is expected to provide protection to at least June 1, 2037, not including possible patent term extension of up to 5 years provided under the Drug Price Competition and Patent Restoration Act. ATH-1017 was discovered and developed in-house at Athira Pharma based on novel data generated within the company.

About ATH-1017
ATH-1017 is a small molecule therapeutic specifically designed to enhance the activity of Hepatocyte Growth Factor (HGF) and its receptor, MET, which are expressed in normal central nervous system function but depleted in Alzheimer's Disease, in order to fight neurodegeneration and regenerate brain tissue. In addition to Alzheimer's disease, ATH-1017 is designed to address the broader dementia population, including Parkinson's disease dementia. ATH-1017's novel mechanism of action is agnostic to the underlying disease pathology of Alzheimer's and other dementias. It is designed to focus on network recovery and synaptic signal transmission in the brain, which has the potential to improve clinical outcomes for patients.

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. We aim 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 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; expectations regarding the potential efficacy and commercial potential of Athira's product candidates; the anticipated presentation 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 and phrases 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 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 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; clinical trials may not demonstrate safety and efficacy of any of Athira's product candidates; Athira's assumptions regarding its planned expenditures and sufficiency of its cash, cash equivalents and investments to fund operations may be incorrect; 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, we may not successfully establish a connection between these P300 latency results and improved cognition; adverse conditions in the general domestic and global economic markets; regulatory uncertainty as a result of the new U.S. administration; 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 expanded product development and clinical activities on operating expenses; 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.

Contact:
Julie Rathbun
Athira Pharma
Julie.rathbun@athira.com
206-769-9219