Athira Pharma Announces Initiation of Patient Dosing for the LIFT-AD Study, a Phase 2/3 Clinical Trial to Evaluate ATH-1017 for Treatment of Mild-to-Moderate Alzheimer's Disease

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-Study to evaluate the safety and efficacy of ATH-1017 to improve mild-to-moderate Alzheimer's disease -

SEATTLE, Oct. 01, 2020 (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 patient dosing has begun in the company's Phase 2/3 clinical trial evaluating ATH-1017, a once-daily investigational drug for the treatment of mild-to-moderate Alzheimer's disease. The clinical trial, known as LIFT-AD (www.lift-adtrial.com), will enroll up to approximately 300 Alzheimer's patients in the United States and Australia.

"Data from our previous study show functional biomarker effects indicating potentially positive effects of ATH-1017 on brain function in Alzheimer's patients," said Hans Moebius, M.D., Ph.D., Chief Medical Officer at Athira. "Our goal is to confirm these compelling effects in a larger ATH-1017 study as there is a significant unmet need for new Alzheimer's treatments."

The Phase 2/3 clinical trial (clinicaltrials.gov identifier NCT04488419) is a randomized, double-blind, placebo-controlled trial evaluating the safety and efficacy of ATH-1017 in individuals with mild-to-moderate Alzheimer's disease. Clinical efficacy will be measured by improvement in cognition and global/functional assessments comparing treatment arms to placebo. Up to approximately 300 patients will be 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.

"Embarking on this trial to evaluate our new approach to treating Alzheimer's is the start of a collective experience that will involve not only individuals with Alzheimer's but their caregivers and family members," said Leen Kawas, Ph.D., President and Chief Executive Officer at Athira. "We appreciate the collaborative efforts that are underway to evaluate the potential of ATH-1017 to improve mild-to-moderate Alzheimer's disease."

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 function with 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 treatment with ATH-1017 compared with those receiving placebo. Through the LIFT-AD clinical trial and other anticipated clinical trials, Athira is seeking to establish a connection between these P300 latency results and improved cognition.

ATH-1017's novel mechanism of action is agnostic to the underlying disease pathology of Alzheimer's and other dementias. It focuses on network recovery and information transmission in the brain, which has the potential to improve clinical outcomes for patients.

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, in order to impact 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.

About Athira Pharma, Inc.
Athira, headquartered in Seattle, 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 and other dementias; Athira's platform technology and potential therapies; future development plans; clinical and regulatory objectives and the timing thereof; anticipated design of planned clinical trials; expectations regarding the potential efficacy and commercial potential of Athira's product candidates, including ATH-1017; the anticipated presentation of data; the results of Athira's research and development efforts 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 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; 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; 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.

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