Athira Pharma Announces Initiation of Patient Dosing in SHAPE, a Phase 2 Clinical Trial of ATH-1017 for the Treatment of Parkinson's Disease Dementia and Dementia with Lewy Bodies

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BOTHELL, Wash., Jan. 25, 2022 (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 SHAPE, a Phase 2 clinical trial of ATH-1017 for the treatment of Parkinson's disease dementia and Dementia with Lewy bodies. 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 initiation of SHAPE is an important milestone in the advancement of our clinical development of ATH-1017. This small molecule is designed to impact neurodegeneration by focusing on network recovery and information transmission in the brain,” said Hans Moebius, M.D., Ph.D., Chief Medical Officer at Athira. “SHAPE incorporates key endpoints to measure cognition, function and behavior, as well as including exploratory endpoints for motor function. We are excited to expand our clinical development of ATH-1017 with the SHAPE trial in other dementia indications that affect so many around the world, beyond Alzheimer’s disease.”

“There is a critical need for new therapeutic approaches that address the neurodegenerative effects experienced by patients with Parkinson’s disease dementia and Dementia with Lewy bodies,” said Daniel Burdick, M.D., SHAPE Principal Investigator and Medical Director at EvergreenHealth. “SHAPE is an important step to advance a novel investigational approach that could potentially restore brain function to patients living with these progressive neurological diseases.”

About SHAPE
SHAPE is a randomized, double-blind, placebo-controlled, parallel-group Phase 2 trial for ATH-1017 in subjects with Parkinson's disease dementia or Dementia with Lewy bodies. The study will enroll approximately 75 individuals in the United States. Study participants are randomized across two dose groups and one placebo group on a 1:1:1 basis to receive a subcutaneous injection of ATH-1017 or placebo once daily over a treatment course of 26 weeks. The primary endpoint for SHAPE is the composite Global Statistical Test, which is an unbiased mathematical algorithm that combines the scores from the cognitive assessment and change in Event-Related-Potential (ERP) P300 latency, a functional measure of working memory processing speed. Additional information on the study can be found at: https://clinicaltrials.gov/ct2/show/NCT04831281.

About ATH-1017
ATH-1017 is a small molecule, specifically designed to enhance the activity of Hepatocyte Growth Factor (HGF) and its receptor, MET. The function of this neuroreceptor system may be impaired under conditions of neurodegeneration. In addition to Alzheimer’s disease, ATH-1017 is designed to address the broader dementia population, including Parkinson’s disease dementia and Dementia with Lewy bodies, as the mechanism of action focuses on network recovery and synaptic signal transmission in the brain, which has the potential to improve clinical outcomes for patients suffering from diverse neurodegenerative conditions.

About Parkinson’s Disease Dementia and Dementia with Lewy Bodies
Nearly 1 million people in the US and more than 10 million people globally are living with Parkinson’s disease (PD). While those with PD commonly experience deficits in motor symptoms, around 50% suffer from Parkinson’s disease dementia (PDD), a progressive neurodegenerative disorder, defined by changes in thinking, memory, and behavior. Only a single therapy is currently approved for PDD, and more specific and novel approaches addressing this disease are needed.

Dementia with Lewy bodies (DLB) is the third most common cause of dementia accounting for 5-15% of all dementia cases globally. In general, DLB and PDD are clinically distinguished by the initial sequence of dementia symptoms.

Both PDD and DLB account for an underserved dementia population. With a lack of specific therapies today for either PDD or DLB, there is a substantial need for a therapy with the potential to slow or stop synaptic loss and neurodegeneration, the main underlying condition contributing to progressive deterioration in dementia symptoms.

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 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 ATH-1017 as a potential treatment for Alzheimer’s disease, Parkinson’s disease dementia, 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 Phase 2 clinical trial of ATH-1017 for treatment of Parkinson’s disease dementia and dementia with Lewy bodies; interactions with regulators and the timing thereof, including anticipated timing of IND or equivalent submissions; 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 ATH-1017 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 ATH-1017 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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