Athira Pharma Presents Overview and Update from ACT-AD and LIFT-AD Trials of ATH-1017 in mild-to-moderate Alzheimer's Disease at CTAD Conference

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– Balanced baseline characteristics in ACT-AD and LIFT-AD to date –
– Topline data from ACT-AD trial targeted for first half of 2022 –

BOTHELL, Wash., Nov. 10, 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 Hans Moebius, M.D., Ph.D., Chief Medical Officer at Athira, presented an overview and updates from two ongoing late-stage clinical trials (ACT-AD and LIFT-AD) with Athira's lead development candidate ATH-1017 in mild-to-moderate Alzheimer's disease, in an oral presentation at the 2021 Clinical Trials on Alzheimer's Disease (CTAD) conference in Boston.

ACT-AD and LIFT-AD are both randomized, double-blind, placebo-controlled, parallel-group 26-week trials evaluating ATH-1017 for the treatment of mild-to-moderate Alzheimer's disease. ATH-1017 is designed to enhance synaptic activity.

"Thus far, baseline characteristics are consistent between ACT-AD and LIFT-AD trials and the average disease severity from both trials is in keeping with the initial Phase 1b AD cohort which showed a statistically significant benefit in Event-Related-Potential (ERP) P300 latency, a functional measure of working memory processing speed. We are encouraged by the safety profile to-date and low early termination rates from both studies as well as the rate of enrollment," said Dr. Moebius. "We expect data read out from the ACT-AD trial, with a primary endpoint of ERP P300 Latency and secondary endpoints measuring cognition, function, and behavior, in the first half of 2022. These results will provide important insights into ATH-1017's treatment effects in Alzheimer's disease."

Study participants in ACT-AD and LIFT-AD are stratified 1:1:1 to receive low dose ATH-1017 (40 mg/day), high dose ATH-1017 (70 mg/day), or placebo. Upon completion of either the ACT-AD or LIFT-AD treatment protocol, those interested may enroll in Athira's Open Label Extension study of ATH-1017. The ACT-AD trial has completed enrollment with topline data expected in the first half of 2022. "We are extremely grateful to the community of patients and researchers participating in this program and sincerely appreciate all that they have done to get us to this point," said Mark Litton, Ph.D., President and Chief Executive Officer at Athira. "Regardless of the root cause of Alzheimer's disease, a therapy that has potential to target the cognitive symptoms caused by neurodegeneration is needed to address the unmet patient need, and ATH-1017 has the potential to meet that need."

The data slides presented during the oral presentation (#OC7) at CTAD can be found on the Athira website on the Events and Presentations page of the Investors section on the company's website at www.athira.com.

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 and dementia with Lewy bodies. ATH-1017 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 ACT-AD
ACT-AD is a randomized, double-blind, placebo-controlled, parallel-group Phase 2 trial for ATH-1017 in subjects with mild-to-moderate Alzheimer's disease. The study has completed enrollment with 77 subjects in the United States and Australia. Study participants were 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 ACT-AD is Event-Related-Potential (ERP) P300 Latency, a functional measure of working memory processing speed, and secondary endpoints measuring cognition, function, and behavior. Additional information on the study can be found at: https://clinicaltrials.gov/ct2/show/NCT04491006. The 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 CTAD conference is solely the responsibility of Athira and does not necessarily represent the official views of the National Institutes of Health.

About LIFT-AD
LIFT-AD is a randomized, double-blind, placebo-controlled, parallel-group Phase 2/3 trial for ATH-1017 for subjects with mild-to-moderate Alzheimer's disease. The study will enroll approximately 300 subjects in the United States, with enrollment ongoing. Subjects 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 LIFT-AD will be measured by the Global Statistical Test, which is a mathematical algorithm that combines the scores from cognition (Alzheimer's Disease Assessment Scale-Cognitive Subscale [ADAS-Cog11]), and either global impression of change (Alzheimer's Disease Cooperative Study-Clinical Global Impression of Change [ADCS-CGIC]), or function (Alzheimer's Disease Cooperative Study-Activities of Daily Living [ADCS-ADL23]). Additional information on the study can be found at: https://clinicaltrials.gov/ct2/show/NCT04488419.

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.

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