Athira Pharma Provides 2022 Pipeline Outlook

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Topline data from ACT-AD Phase 2 Alzheimer's disease study in 2Q22

LIFT-AD Phase 3 Alzheimer's disease study sample size increased to strengthen statistical power of co-key secondary endpoints and enhance the potential for a single pivotal clinical study

Milestones achieved with initiation of SHAPE Phase 2 Parkinson's disease dementia clinical trial and IND filing for ATH-1020

BOTHELL, Wash., Jan. 05, 2022 (GLOBE NEWSWIRE) -- Athira Pharma, Inc. (NASDAQ: ATHA), a late clinical-stage biopharmaceutical company focused on developing small molecules to restore neuronal health and slow neurodegeneration, today provided an update on its clinical programs and outlook for 2022.

"Our progress in 2021 provides a strong foundation for an exciting 2022, including topline data from the ACT-AD trial of ATH-1017. Enrollment in the LIFT-AD study continues to exceed industry benchmarks, and to take advantage of this momentum, we are increasing enrollment of mild-to-moderate Alzheimer's disease participants in this study to strengthen the statistical power of key secondary endpoints, which include cognition, function and behavior, with anticipated topline data readout in the first half of 2023," stated Mark Litton, Ph.D., President and Chief Executive Officer of Athira. "We have initiated our SHAPE Phase 2 clinical study of ATH-1017 in Parkinson's disease dementia and Dementia with Lewy bodies. Furthermore this quarter, we will begin a clinical study of ATH-1020, which is targeted for neuropsychiatric diseases."

"While the trial design for LIFT-AD, including the primary composite endpoint Global Statistical Test, remains unchanged, the opportunistic addition of approximately 120 patients strengthens the statistical power of co-key secondary endpoints which we believe enhances the potential for a single pivotal clinical study," said Hans Moebius, MD, PhD, Chief Medical Officer of Athira. "The increased sample size and resulting power for ADAS-Cog11 is based on our original statistical modeling and consistent with the design of previous Phase 3 trials in the treatment of mild-to-moderate Alzheimer's disease. As planned, we will leverage insights from the ACT-AD trial results in the second quarter to optimize the analysis plan for LIFT-AD."

Athira's 2022 Pipeline Outlook: Status and Upcoming Milestones:

ATH-1017 - Small molecule designed to enhance the activity of hepatocyte growth factor (HGF) and its receptor, MET, to impact neurodegeneration and regenerate brain tissue.

ACT-AD Phase 2 Study* in mild-to-moderate Alzheimer's disease (NCT04491006)

- Enrollment in ACT-AD completed in October 2021 with 77 participants with mild-to-moderate Alzheimer's disease enrolled across 14 sites in the United States and Australia. The primary endpoint for ACT-AD is Event-Related-Potential (ERP) P300 Latency, a functional measure of working memory processing speed, and secondary endpoints measure cognition, function, and behavior.
- Athira is on track to report top-line data in the second quarter of 2022.

LIFT-AD Phase 3 Study in mild-to-moderate Alzheimer's Disease (NCT04488419)

- Recruitment in the LIFT-AD trial is progressing well, with over 200 participants currently enrolled.
- Athira is increasing the study sample size by approximately 120 participants, from 300 to 420, in order to strengthen the statistical power of co-key secondary endpoints, including ADAS-Cog11.
- Based on the enrollment momentum in this study to-date, the company anticipates enrollment completion in the third quarter of 2022 and to report top-line data in the first half of 2023.

SHAPE Phase 2 Study in mild-to-moderate Parkinson's disease dementia and Dementia with Lewy bodies (NCT04831281)

- Athira initiated the SHAPE trial in the fourth quarter of 2021. SHAPE is a randomized, double-blind, placebo-controlled, parallel-group Phase 2 proof-of-concept study of ATH-1017 in approximately 75 participants with mild-to-moderate Parkinson's disease dementia or Dementia with Lewy bodies.
- The company expects to dose the first patient in the SHAPE Phase 2 study in the first quarter of 2022.

ATH-1020 - Orally available, small brain-penetrant molecule designed to enhance the HGF/MET system, as a potential treatment candidate for neuropsychiatric indications.

Phase 1 Study in Healthy Volunteers (NCT05169671)

- Athira submitted an Investigational New Drug application for ATH-1020 in the fourth quarter of 2021. The Phase 1 study will evaluate the safety, tolerability, and pharmacokinetics of ATH-1020 in approximately 68 healthy young and elderly volunteers.

- The company expects to dose the first volunteer in the study in the first quarter of 2022.

*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 is solely the responsibility of Athira and does not necessarily represent the official views of the National Institutes of Health.

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 disease 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 and ATH-1020 as a potential treatment for neuropsychiatric indications; 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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