Athira Pharma Provides 2023 Pipeline Outlook

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Advancing small molecule therapeutic candidates with clinical and preclinical data suggesting potential neuroprotective, neurotrophic, procognitive and disease-modifying effects

Fosgonimeton Phase 2/3 LIFT-AD study in mild-to-moderate Alzheimer's disease is progressing with targeted enrollment completion in mid-2023 and topline data in early 2024

ATH-1105 candidate for amyotrophic lateral sclerosis (ALS) is targeted for IND filing in 2023

BOTHELL, Wash., Jan. 05, 2023 (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 pipeline development programs and outlook for 2023.

"Our dedication to advancing new therapeutics to impact neurodegenerative diseases remains steadfast. The totality of our data shared in 2022 strengthens our confidence in and supports the potential of our small molecule approach targeting the HGF/MET system for diseases including Alzheimer's, Parkinson's, and ALS. The consistency of data from preclinical models across various neurodegenerative diseases and in Alzheimer's patients suggest that our small molecule product candidates may be neuroprotective, neurotrophic, procognitive and potentially disease-modifying. This includes our recently published preclinical results in the peer-reviewed journal, *Neurotherapeutics*, supporting the potential of fosgonimeton," stated Mark Litton, Ph.D., President and Chief Executive Officer of Athira Pharma.

"Athira has an exciting year ahead. We believe the independent, unblinded interim efficacy and futility analysis of the Phase 2/3 LIFT-AD study mitigates fosgonimeton program risk, supports the potential clinical benefits of fosgonimeton treatment, and underscores the rationale for continued development of this promising potential new therapy. We expect to complete enrollment of the LIFT-AD study for mild-to-moderate Alzheimer's disease in mid-2023. Additionally, this year we look forward to filing an IND application for ATH-1105 as a potential treatment for ALS.

"We also plan to publish and present additional data that further support that HGF/MET enhancement may play an important role in treating neurodegenerative disease. Importantly, we have a strong balance sheet that enables us to continue to explore the potential of fosgonimeton in Alzheimer's and Parkinson's disease dementia and dementia with Lewy body and to advance other programs, such as ATH-1105 in ALS, through to key inflection points," concluded Dr. Litton.

Athira's 2023 Pipeline Outlook: Status and Upcoming Milestones

Fosgonimeton (ATH-1017) - Small molecule designed to enhance the activity of hepatocyte growth factor (HGF) and its receptor, MET, with the potential to protect and repair neural networks.

LIFT-AD Phase 2/3 Study in mild-to-moderate Alzheimer's Disease (NCT04488419)

- Following results from the exploratory Phase 2 ACT-AD trial, Athira proactively amended the entry criteria for the LIFT-AD trial in September 2022 to investigate the effects of fosgonimeton compared with placebo, without background therapy.
- In October 2022, following an unblinded interim efficacy and futility analysis, an independent data monitoring committee recommended continuation of the LIFT-AD study in patients with mild-to-moderate AD.
- The committee also determined that, with the additional enrollment of fewer than 150 patients for a total enrollment of less than 300 patients without background therapy, the study will be well powered for the primary endpoint given the preliminary effect size observed.
- The Company expects to complete enrollment of the LIFT-AD study in mid-2023 and to report topline data in early 2024.

Open Label Extension (OLEX) study (NCT04886063)

- The Open Label Extension (OLEX) study for the ACT-AD and LIFT-AD studies continues, with more than 200 patients currently enrolled. As of year-end 2022, greater than 85 percent of patients who have completed either study have elected to participate in the OLEX study.

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

- Athira enrolled 28 patients in the exploratory Phase 2 SHAPE study of fosgonimeton in participants with Parkinson's disease dementia or Dementia with Lewy bodies.

- The Company expects to complete the treatment of the 28 patients and to evaluate the learnings from these results to determine next steps for this program.
- With the compelling preclinical data recently presented on the broader potential of fosgonimeton to improve motor function in Parkinson's disease, the Company will seek to evaluate study designs that will further explore its potential in this complex disease.

ATH-1020 - Orally available, small molecule designed to enhance the HGF/MET system, as a potential treatment candidate for neuropathic pain or neurodegenerative disorders.

Phase 1 Study in Healthy Volunteers (NCT05169671)

- The Company completed the Phase 1, single-ascending, dose escalation study of ATH-1020.
- ATH-1020 demonstrated a favorable safety profile and was well tolerated in healthy volunteers.
- The Company plans to evaluate its options with this compound and will consider its advancement in relation to other opportunities and resources.

ATH-1105 – A small molecule positive modulator of the HGF/MET system as a potential treatment candidate for ALS.

- The Company presented preclinical data in December 2022.
- ATH-1105 demonstrated consistent improvements across measures of motor function, nerve function, and neurodegeneration in a TDP-43 mouse model of ALS.
- The Company plans to submit an IND application with the U.S. Food and Drug Administration in 2023 in order to initiate first-in-human studies of this promising product candidate as a treatment for ALS.

Financial Position

- Athira reported cash, cash equivalents and investments of $260.0 million as of September 30, 2022.

About Athira Pharma, Inc.
Athira Pharma, Inc., headquartered in the Seattle, Washington area, is a late clinical-stage biopharmaceutical company focused on developing small molecules to restore neuronal health and slow neurodegeneration. Athira aims to provide rapid cognitive improvement and alter the course of neurological diseases with its novel mechanism of action. Athira is currently advancing its pipeline therapeutic candidates targeting the HGF/MET neurotrophic system for Alzheimer's and Parkinson's disease, Dementia with Lewy bodies and amyotrophic lateral sclerosis (ALS). For more information, visit www.athira.com. You can also follow Athira on Facebook, LinkedIn and @athirapharma on Instagram.

Forward-Looking Statements
This communication 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: product candidates as a potential treatment for Alzheimer's disease, Parkinson's disease dementia, Dementia with Lewy bodies, neuropsychiatric diseases, and other neurodegenerative diseases, such as amyotrophic lateral sclerosis; Athira's platform technology and potential therapies; future development plans; clinical and regulatory objectives and the timing thereof; expectations regarding the potential efficacy and commercial potential of Athira's product candidates; 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," "on track," "would," "expect," "plan," "believe," "intend," "pursue," "continue," "suggest," "potential," 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 data for our product candidates from our preclinical and clinical trials not supporting the safety, efficacy and tolerability of our product candidates; cessation or delay of Athira's development of product candidates may occur; future potential regulatory milestones for product candidates, 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 the regulatory process for Athira product candidates; Athira may not be able to recruit sufficient patients for its clinical trials; the outcome of legal proceedings that 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; possible negative interactions of Athira's product candidates with other treatments; Athira's assumptions regarding the sufficiency of its cash, cash equivalents and investments to fund its planned operations may be incorrect; adverse conditions in the general domestic and global economic markets; the impact of competition; 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 expanded product development and clinical activities on operating expenses; the 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.

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