Athira Pharma Completes Enrollment of Phase 2/3 LIFT-AD Clinical Trial of Fosgonimeton in Mild-to-Moderate Alzheimer's Disease

January 3, 2024

Topline data from LIFT-AD on track for second half of 2024

Previously reported independent, unblinded interim analysis supports trial continuation and potential clinically meaningful activity of fosgonimeton

Potential first-in-class approach focused on HGF modulation for treatment of neurodegenerative diseases

BOTHELL, Wash., Jan. 03, 2024 (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 announced completion of enrollment in the Phase 2/3 LIFT-AD clinical trial of fosgonimeton as a potential treatment for mild-to-moderate Alzheimer's disease.

Fosgonimeton is a potentially first-in-class, investigational, small molecule designed to positively modulate the hepatocyte growth factor (HGF) system, which can activate neuroprotective, neurotrophic and anti-inflammatory pathways in the central nervous system.

"The successful completion of enrollment in LIFT-AD marks an important milestone for Athira and enables the topline data readout in the second half of 2024," said Mark Litton, Ph.D., President and Chief Executive Officer of Athira. "We believe LIFT-AD has the potential to meet the study's primary endpoint based on the unblinded interim efficacy and futility analysis performed by an independent committee on the first 100 patients who completed the trial. This interim analysis gives us confidence in a potentially positive outcome for LIFT-AD, as stringent evaluation criteria were applied based on validated and clinically meaningful cognitive and functional outcomes."

"We are also encouraged that more than 85% of participants who completed the LIFT-AD and ACT-AD clinical trials elected to participate in the open label extension trial (OLEX). Notably, there are currently more than 60 patients in this open label trial who are continuing fosgonimeton treatment beyond 18 months, which is unexpected in a progressive mild-to-moderate Alzheimer's disease population. We also recently reported findings from the exploratory SHAPE Phase 2 clinical trial, which investigated the use of fosgonimeton in patients with Parkinson's disease dementia and dementia with Lewy Bodies. The results showed positive effects on several cognitive measures in the fosgonimeton 40 mg dose group, which is the same dose being investigated in the LIFT-AD trial. Collectively, the extended duration of OLEX participation and the SHAPE findings add to our confidence for a positive LIFT-AD outcome and support the potential of our HGF modulation franchise in neurodegeneration," added Dr. Litton.

The Phase 2/3 LIFT-AD clinical trial, which targeted an enrollment of 298 patients in the primary analysis population, ultimately enrolled approximately 315 patients with mild-to-moderate Alzheimer's disease in a 26-week, randomized, double-blind, placebo-controlled clinical trial evaluating once-daily subcutaneous injections of fosgonimeton 40 mg compared to placebo. The primary endpoint is the Global Statistical Test (GST), a composite of the co-key secondary endpoints ADAS-Cog11 and ADCS-ADL23. Key secondary and exploratory endpoints include changes in plasma biomarkers of neurodegeneration, protein pathology, and neuroinflammation. Additional information about the LIFT-AD study can be found at: NCT04488419.

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 alter the course of neurological disease by advancing its pipeline of therapeutic candidates targeting the neurotrophic HGF system for Alzheimer's and Parkinson's disease, Dementia with Lewy bodies, and amyotrophic lateral sclerosis. For more information, visit www.athira.com. You can also follow Athira on Facebook, LinkedIn and @athirapharma on X, formerly known as Twitter, and 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, Parkinson's disease dementia, Dementia with Lewy bodies, and other neurodegenerative diseases, such as amyotrophic lateral sclerosis; future development plans; the anticipated reporting of data; the potential learnings from the SHAPE trial and LIFT-AD unblinded interim efficacy and futility analysis and their ability to inform and improve future clinical development plans; 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 from preclinical and clinical trials may not support the safety, efficacy and tolerability of Athira's product candidates; development of product candidates may cease or be delayed; regulatory authorities could object to protocols, amendments and other submissions; 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; 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 Athira, its directors and officers; 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 pandemics or health epidemics, 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 from time to time. 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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