Alector Announces First Patient Dosed in PROGRESS-AD Phase 2 Clinical Trial of AL101/GSK4527226 in Patients with Early Alzheimer's Disease

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The trial, being conducted in partnership with GSK, is expected to enroll approximately 282 patients globally

SOUTH SAN FRANCISCO, Calif., Feb. 08, 2024 (GLOBE NEWSWIRE) -- Alector, Inc. (Nasdaq: ALEC) and GSK plc (LSE/NYSE: GSK) today announced that the first patient has been dosed in PROGRESS-AD, the global Phase 2 clinical trial of AL101/GSK4527226 in patients with early Alzheimer's disease (AD), including mild cognitive impairment and mild dementia due to AD. AL101 is an investigational human monoclonal antibody designed to block and downregulate the sortilin receptor to elevate the level of progranulin in the brain in a manner similar to investigational latozinemab but with different pharmacokinetic (PK) and pharmacodynamic (PD) properties. Alector and GSK are co-developing and will be co-commercializing AL101 for the potential treatment of more prevalent neurodegenerative diseases, including AD and Parkinson's disease.

"In partnership with GSK, we are delighted to announce the dosing of the first patient in PROGRESS-AD, the Phase 2 trial of AL101 for the treatment of early Alzheimer's disease, which remains a high unmet need," said Arnon Rosenthal, Ph.D., Chief Executive Officer of Alector. "Modest reduction in the levels of progranulin due to genetic mutations has been shown to be associated with an increased risk of developing Alzheimer's disease. Conversely, an elevation of progranulin was shown to be protective in animal models of Alzheimer's disease. This provides a genetic and biological rationale for considering the investigational testing of AL101 in Alzheimer's disease. To date, AL101 has been shown to be generally well tolerated and elevated progranulin levels in healthy volunteers. We look forward to continuing the development of AL101 in this Phase 2 trial with our partner GSK who is operationalizing the trial. AL101 is an exciting addition to our expanding portfolio of investigational dementia therapies, which includes the TREM2-activating antibody AL002, currently in the final stages of a Phase 2 trial in Alzheimer's disease, and latozinemab, a progranulin-elevating antibody, advancing through the final stages of a pivotal Phase 3 trial in frontotemporal dementia due to a progranulin gene mutation."

PROGRESS-AD is a randomized, double-blind, placebo-controlled Phase 2 clinical trial of AL101 enrolling approximately 282 patients with early Alzheimer's disease at multiple sites globally. The 76-week study is designed to assess the safety and efficacy of two dose levels of AL101 compared to placebo. Participants will be randomized to one of three treatment groups, receiving AL101 or placebo intravenously. The primary endpoint of the study is disease progression as measured by the Clinical Dementia Rating Sum of Boxes (CDR®-SB). The CDR-SB is a validated instrument that tracks the progression of cognitive impairments in various categories. The trial also employs other clinical and functional outcome assessments.

The Phase 1 study of AL101 was a randomized, double-blind, placebo-controlled study in 88 healthy volunteers who received either single or multiple doses of AL101 administered intravenously (IV) or subcutaneously (SC). The study found that AL101 was generally well tolerated and increased progranulin (PGRN) levels in plasma and cerebrospinal fluid (CSF) in a dose-dependent manner. The study results demonstrated that the PK and PD profile supported the progression to Phase 2 clinical trials for more prevalent neurodegenerative conditions, such as AD and Parkinson's disease.

Additional information about PROGRESS-AD (NCT06079190) may be found at ClinicalTrials.gov.

About AL101

AL101 is an investigational human monoclonal antibody designed to elevate the level of progranulin, a regulator of immune activity in the brain with genetic links to multiple neurodegenerative disorders. Mutations that moderately reduce the expression levels of progranulin have been shown to increase the risk of developing Alzheimer's disease and Parkinson's disease. Increased progranulin levels have been demonstrated to be protective for these diseases in animal models.

Collaboration with GSK

In July 2021, Alector entered into a collaboration and license agreement with GSK (NYSE: GSK) to collaborate on the global development and commercialization of progranulin-elevating monoclonal antibodies, including investigational candidates latozinemab and AL101 for a range of neurodegenerative diseases, including frontotemporal dementia, amyotrophic lateral sclerosis, Alzheimer's disease, and Parkinson's disease. Under the terms of the GSK agreement, Alector received $700 million in upfront payments. In addition, Alector may be eligible to receive up to an additional $1.5 billion in clinical development, regulatory, and commercial launch-related milestone payments. In the United States, the companies will equally share profits and losses from commercialization of latozinemab and AL101. Outside of the United States, Alector will be eligible for double-digit tiered royalties.

About Alector

Alector is a clinical-stage biotechnology company pioneering immuno-neurology, a novel therapeutic approach for the treatment of neurodegenerative diseases. Immuno-neurology targets immune dysfunction as a root cause of multiple pathologies that are drivers of degenerative brain disorders. Alector has discovered and is developing a broad portfolio of innate immune system programs, designed to functionally repair genetic mutations that cause dysfunction of the brain's immune system and enable rejuvenated immune cells to counteract emerging brain pathologies. Alector's immuno-neurology product candidates are supported by biomarkers and seek to treat indications, including Alzheimer's disease and genetically defined frontotemporal dementia patient populations. Alector is headquartered in South San Francisco, California. For additional information, please visit www.alector.com.

About GSK

GSK is a global biopharma company with a purpose to unite science, technology, and talent to get ahead of disease together. Find out more at gsk.com.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements in this press release include, but are not limited to, statements regarding our product candidates, our and our investigators' judgments and beliefs regarding the observed safety and efficacy to date of our product candidates, planned and ongoing preclinical studies and clinical trials, expected milestones, including the timing of data from the PROGRESS-AD Phase 2 trial, and expectations of our collaborations. Such statements are subject to numerous risks and uncertainties, including but not limited to risks and uncertainties as set forth in Alector's Quarterly Report on Form 10-Q filed on November 7, 2023, with the Securities and Exchange Commission ("SEC"), as well as the other documents Alector files from time to time with the SEC. These documents contain and identify important factors that could cause the actual results for Alector to differ materially from those contained in Alector's forward-looking statements. Any forward-looking statements contained in this press release speak only as of the date hereof, and Alector specifically disclaims any obligation to update any forward-looking statement, except as required by law.

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