Trial will enroll up to 180 symptomatic and pre-symptomatic participants with FTD-GRN gene mutation at multiple sites in the U.S., Europe and Australia

There are currently no FDA-approved treatments for frontotemporal dementia

SOUTH SAN FRANCISCO, Calif., July 24, 2020 (GLOBE NEWSWIRE) -- Alector, Inc. (Nasdaq: ALEC), a clinical-stage biotechnology company pioneering immuno-neurology, today announced dosing of the first patient in its pivotal Phase 3 clinical trial, named INFRONT-3, evaluating AL001 in people at risk for or with frontotemporal dementia due to a progranulin gene mutation (FTD-GRN). AL001 is the company’s wholly owned, investigational human monoclonal antibody designed to modulate progranulin, a key regulator of immune activity in the brain.

Frontotemporal Dementia (FTD) is a rapidly progressing and severe form of dementia found most frequently in people less than 65 years old at the time of diagnosis. It affects 50,000 to 60,000 people in the United States and roughly 110,000 in the European Union. There are multiple heritable forms of FTD, and FTD-GRN patients represent 5% to 10% of all people with FTD. There are currently no approved treatments options available for FTD.

“The initiation of our global pivotal Phase 3 trial of AL001 is a significant step towards achieving our mission of helping patients suffering from FTD and other neurodegenerative diseases,” said Robert Paul, M.D., Ph.D., chief medical officer of Alector. “Our Phase 3 study has been designed to measure slowing of disease progression in both symptomatic and pre-symptomatic FTD-GRN patients. We believe the INFRONT-3 trial will successfully demonstrate AL001’s ability to significantly alter the course of FTD and potentially transform the lives of people affected by this condition. We are incredibly grateful to the patients, healthcare professionals and clinical sites that participated during earlier phases of study, allowing us to rapidly progress to Phase 3 evaluation in less than two years.”

The randomized, double-blind, placebo-controlled trial will enroll up to 180 FTD-GRN mutation carriers across approximately 50 sites in the United States, Europe and Australia. Symptomatic and pre-symptomatic participants will be randomized to receive AL001 or placebo intravenously every four weeks. Participants will also be given the option to continue receiving treatment in an open-label extension study.

The primary endpoint of the pivotal Phase 3 trial is to measure the effect of AL001 on clinical decline by utilizing the CDR® plus NACC FTLD-SB assessment, which evaluates clinical impairments in behavior, language, memory, judgment, and functional activities in trial participants. In addition, the trial will assess secondary clinical endpoints, multiple biomarkers and safety.

To learn more about the Phase 3 trial, please visit https://clinicaltrials.gov/.

About AL001
AL001 is a wholly owned, investigational human monoclonal antibody designed to modulate progranulin, a key regulator of immune activity in the brain with genetic links to multiple neurodegenerative disorders, including FTD, Alzheimer’s disease, and Parkinson’s disease. AL001 aims to increase the level of progranulin in humans by inhibiting a progranulin degradation mechanism. AL001 was discovered and engineered in collaborative effort between Alector and Adimab, LLC.

AL001 has received Orphan Drug designation for the treatment of FTD and Fast Track designation for the treatment of FTD-GRN from the U.S. Food and Drug Administration.

About Frontotemporal Dementia (FTD)
FTD is a rapidly progressing and severe form of dementia found most frequently in people less than 65 years old at the time of diagnosis. It affects 50,000 to 60,000 people in the United States and roughly 110,000 in the European Union. There are currently no FDA-approved treatments options for FTD.

There are multiple heritable forms of FTD. In one form, FTD-GRN, people have a mutation in the progranulin gene. This population represents 5% to 10% of all people with FTD. Mutations in a single copy of progranulin gene (GRN) leads to a 50% or greater decrease in the level of progranulin and invariably leads to development of FTD. In another form, FTD-C9orf72, people with mutations in the C9orf72 gene can develop FTD, which represents approximately 5% to 10% of all people with FTD. FTD-C9orf72 is associated with abnormal accumulation of the protein TDP-43, which is also a hallmark pathology found in FTD-GRN.

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 is developing a broad portfolio of programs designed to functionally repair genetic mutations that cause dysfunction of the brain’s immune system and enable the rejuvenated immune cells to counteract emerging brain pathologies. The Company’s product candidates are supported by biomarkers and target genetically defined patient populations in frontotemporal dementia and Alzheimer’s disease. Alector is headquartered in South San Francisco, California. For additional information, please visit www.alector.com.

Forward-Looking Statements
This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Such statements are subject to numerous important factors, risks and uncertainties that may cause actual events or results to differ materially from current expectations and beliefs, including but not limited to risks and uncertainties related to the Company’s plans for and anticipated benefits and mechanism of the
Company's product candidates, the timing and objectives of the Company's clinical studies and anticipated regulatory and development milestones, Alector and its business as set forth in Alector's Annual Report on Form 10-Q filed with the Securities and Exchange Commission (the “SEC”) on May 13, 2020, 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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