Alector Initiates Phase 2 Trial of AL001 in Patients with Frontotemporal Dementia

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SOUTH SAN FRANCISCO, Calif., Sept. 09, 2019 (GLOBE NEWSWIRE) -- Alector, Inc. (Nasdaq: ALEC), a clinical stage biotechnology company pioneering immuno-neurology, today announced the initiation of patient screening and enrollment for the INFRONT Phase 2 clinical trial for its product candidate AL001. AL001 is being evaluated for the treatment of people with frontotemporal dementia (FTD) with specific genetic mutations, including the granulin gene (FTD-GRN).

"We are encouraged by the recent data from our Phase 1b trial of AL001, in which AL001 was well-tolerated and restored progranulin back to normal physiological levels in the central nervous system of FTD-GRN patients," said Robert Paul, M.D, Ph.D., chief medical officer of Alector. "In this Phase 2 trial, we plan to enroll up to 32 patients and gain important insights into AL001's safety and activity in this patient population as we prepare for our pivotal Phase 3 study in 2020."

The Phase 2 trial will assess the longitudinal safety, tolerability, pharmacokinetics and pharmacodynamics of AL001, as well as its effects on biomarkers of neurodegeneration and on cognition. The study will enroll FTD-GRN patients and an additional cohort of FTD patients with a C9orf72 mutation (FTD-C9orf72).

"FTD is a devastating brain disorder that leads to a rapid and progressive decline of brain function in affected individuals and for which no treatment exists today. AL001 is a completely novel approach for the treatment of FTD, and the initiation of Alector's Phase 2 trial is an important step forward for the afflicted individuals with a particular genetic form of FTD, their families, and the healthcare community," said Brad Boeve, M.D., chair of Behavioral Neurology at Mayo Clinic and one of the leading primary investigators for the INFRONT study.

About the INFRONT Phase 2 Study
The INFRONT Phase 2 multicenter, open-label clinical trial of AL001 is designed to assess the safety, tolerability, pharmacokinetics, pharmacodynamics and the effect on clinical outcome assessments (COAs) in frontotemporal dementia patients with a granulin or C9orf72 mutation. AL001 will be administered intravenously every four weeks over at least a 48-week dosing period. To learn more about this study, please visit www.clinicaltrials.gov and reference study number NCT03987295. An open-label extension study is planned to be offered to study participants following completion of this Phase 2 trial.

ARTFL-LEFFTDS and GENFI investigators are valued partners to Alector and to the patients participating in the INFRONT Phase 2 study.

About Frontotemporal Dementia (FTD)
FTD is a rapidly progressing and severe form of dementia found most frequently in individuals less than 65 years old at the time of diagnosis. It affects 50,000 to 60,000 individuals in the United States and roughly 110,000 individuals in the European Union, with potentially higher prevalence in Asia and Latin America. There is currently no approved treatment available for FTD patients.

There are multiple heritable forms of FTD. In one form, FTD-GRN, patients have a mutation in the progranulin gene. This population represents 5% to 10% of all patients with FTD. Mutations in a single copy of progranulin leads to a 50% or greater decrease in the level of progranulin and invariably leads to development of FTD. To date researchers have identified more than 70 inherited loss of function mutations in the progranulin gene that lead to FTD. In another form, FTD-C9orf72, people with mutations in the C9orf72 gene can develop FTD, which represents 5% to 10% of all patients with FTD. FTD-C9orf72 is associated with abnormal accumulation of the protein TDP-43, which is also a hallmark in FTD-GRN.

About AL001
AL001 is Alector's wholly-owned human monoclonal antibody designed to modulate progranulin, a regulator of immune activity in the brain with genetic links to multiple neurodegenerative disorders, including FTD, Alzheimer's disease, and Parkinson's disease. It 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 was granted Orphan Drug designation by the U.S. Food and Drug Administration for the treatment of FTD in June 2018.

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.

Cautionary Note Regarding Forward-Looking Statements
This press release contains "forward-looking" statements within the meaning of The Private Securities Litigation Reform Act of 1995. Such forward-looking statements are based on our beliefs and assumptions and on information currently available to us on the date of this press release. Forward-looking statements may involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from those expressed or implied by the forward-looking statements. These statements include, but are not limited to, statements regarding 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. Except as required by law, we assume no obligation to update these forward-looking statements publicly, or to update the reasons actual results could differ materially from those anticipated in the forward-looking statements, even if new information becomes available in the future. Important factors that could cause our actual results to differ materially are detailed from time to time in the reports Alector files with the Securities and Exchange Commission, including in our quarterly report on

Form 10-Q that is filed with the Securities and Exchange Commission (“SEC”). Copies of reports filed with the SEC are posted on Alector’s website and are available from Alector without charge.

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