Alector Announces FDA Fast Track Designation Granted to AL101 for the Treatment of Patients with Frontotemporal Dementia

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SOUTH SAN FRANCISCO, Calif., Feb. 05, 2020 (GLOBE NEWSWIRE) -- Alector, Inc. (Nasdaq: ALEC), a clinical-stage biotechnology company pioneering immuno-neurology, today announced that the U.S. Food and Drug Administration (FDA) has granted Fast Track designation to AL101 for the treatment of patients with progranulin gene mutations causative of frontotemporal dementia (FTD-GRN). AL101, the company's second product candidate designed to restore progranulin levels in the brain, is currently being evaluated in a Phase 1 trial in healthy volunteers.

"There is a clear and validated connection between progranulin expression in the brain and certain neurodegenerative disorders like FTD, Alzheimer's disease and Parkinson's disease. At Alector, we are pioneering the development of therapies targeting the progranulin pathway, with two product candidates being tested in clinical trials," said Robert King, Ph.D., chief development officer at Alector. "AL101 is the second product candidate from our progranulin program to receive Fast Track designation from the FDA, underscoring the need for new treatment options for these patients. We look forward to working with the agency to advance AL101 as quickly as possible."

Fast Track designation is designed to facilitate the development and expedite the review of therapies for serious conditions and fill an unmet medical need. Programs with Fast Track designation may benefit from early and frequent communications with the FDA, potential priority review, and additionally a rolling submission of the marketing application.

About AL101
AL101 is Alector's wholly-owned human monoclonal antibody and second product designed to restore levels of progranulin in the central nervous system. Progranulin is 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, and increased progranulin levels have been demonstrated to be protective for these diseases in animal models.

AL101 has the potential to be developed for the treatment of frontotemporal dementia, Alzheimer's disease and Parkinson's disease. AL101 received orphan drug designation from the U.S. Food and Drug Administration for the treatment of frontotemporal dementia in July 2019 and Fast Track designation in February 2020.

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 forward-looking statements include, but are not limited to, the ability and timing for the closing of the public offering of common stock. 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 market conditions and satisfaction of customary closing conditions related to the proposed offering, and other risks and uncertainties related to the offering, Alector and its business as set forth in Alector's registration statement on Form S-1 filed with the Securities and Exchange Commission (the "SEC") on January 29, 2020 and the preliminary prospectus included therein, as well as the other documents Alector files from time to time with the SEC, including Alector's most recent Quarterly Report on Form 10-Q filed with the SEC on November 12, 2019. 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.

Source: Alector, Inc.

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