Alector Receives Orphan Drug Designation from the U.S. FDA for AL001 for the Treatment of Frontotemporal Dementia

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SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Alector, a privately held biotechnology company focused on developing therapies that harness the immune system to cure neurodegenerative diseases and cancer, today announced that the U.S. Food and Drug Administration Office of Orphan Products Development has granted orphan drug designation to AL001, a human recombinant monoclonal antibody, for the treatment of all patients with frontotemporal dementia (FTD).

“There are currently no approved therapies to address the underlying cause and needs of FTD patients. In addition, given the marked behavioral and personality changes associated with FTD, coupled with the early onset of the disease, the care of FTD patients is a significant challenge for families and the society,” said Robert Paul, chief medical officer, Alector. “The granting of orphan drug designation is a significant milestone for the AL001 development program, and we are excited to work with leaders and experts in the research, medical and patient advocate communities to bring AL001 to the patients suffering from this disease.”

“FTD is caused in part by a dysfunctional brain immune system, and AL001 is one of our immuno-neurology drugs designed to repair that immune system to elicit a therapeutic benefit. We believe that our immuno-neurology approach could potentially have as much impact on brain disorders as immuno-oncology drugs have had on cancer patients,” said Arnon Rosenthal, Ph.D., chief executive officer, Alector.

About Orphan Drug Designation

The U.S. Food and Drug Administration’s Orphan Drug Designation program provides orphan status to drugs and biologics that are defined as those intended for the safe and effective treatment, diagnosis or prevention of rare diseases/disorders that affect fewer than 200,000 people in the U.S., or that affect more than 200,000 persons but are not expected to recover the costs of developing and marketing a treatment drug. Orphan Drug Designation qualifies the sponsor of the drug candidate for various development incentives, which may include tax credits for qualified clinical testing, an exemption from fees under the Prescription Drug User Fee Act (PDUFA), and a seven-year marketing exclusivity period following approval.

About Frontotemporal Dementia

Frontotemporal dementia (FTD) is the second most common early-onset form of dementia after Alzheimer’s disease, afflicting approximately 60,000 Americans and 110,000 people in Europe. FTD is a rare but rapidly progressing degenerative syndrome and is characterized by prominent cognitive dysfunction, behavioral and personality changes, and language deficits. Patients with FTD progress rapidly and inexorably to death in less than 10 years from its onset.

About AL001

AL001 is Alector’s wholly owned human monoclonal antibody designed to increase the levels of progranulin in the brain, a secreted immune modulatory factor which when mutated leads to frontotemporal dementia (FTD).

About Alector

Alector is a privately held biotechnology company whose mission is to develop immuno-neurology and immuno-oncology therapies to treat neurodegenerative diseases and cancer. Alector is headquartered in South San Francisco, Calif. For more information, please visit www.alector.com.

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