Alector Presents New Data from Multiple Pipeline Programs at 2021 CTAD Conference

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SOUTH SAN FRANCISCO, Calif., Nov. 10, 2021 (GLOBE NEWSWIRE) -- Alector, Inc. (Nasdaq: ALEC), a clinical-stage biotechnology company pioneering immuno-neurology, shared data from its AL003 and AL101 programs in poster presentations at the 14th Clinical Trials on Alzheimer's Disease (CTAD) conference being held November 9-12, 2021, virtually and in Boston.

“Since our formation, Alector has established a deep pipeline of therapeutic immuno-neurology candidates, each of which aims to harness the body’s innate immune system to slow the progression of neurodegenerative diseases. The presentations at this year’s CTAD conference highlight the diverse genetically validated targets we have in our portfolio and the progress being achieved across our pipeline,” said Sam Jackson, interim Chief Medical Officer of Alector. “We’re presenting data from two Phase 1 clinical-stage candidates, AL003 and AL101, each with a distinct profile. AL003 has a mechanism analogous to the checkpoint inhibitors used in oncology and is intended to restore appropriate innate immune system function and allow the brain’s immune cells to do their job in maintaining a healthy equilibrium. AL101 builds on the success we’ve observed with our lead candidate, AL001, with the intent of offering optimized dosing while increasing progranulin levels. We will continue to advance both candidates into further clinical studies in the coming months.”

Alector management will host a conference call to review and discuss data presented this week for four of its pipeline candidates at the CTAD conference and at the Society for Immunotherapy of Cancer (SITC) on November 12, 2021, at 4:00 p.m. ET.

AL003: Phase 1 Data in Healthy Volunteers and Participants with Alzheimer’s Disease
AL003 is a humanized monoclonal antibody that targets Siglec3 (sialic acid binding Ig-like lectin 3), or CD33, a transmembrane receptor expressed by microglia cells in the brain. The Phase 1 INTERCEPT (NCT03822208) study is a randomized, placebo-controlled trial evaluating the safety, tolerability, pharmacokinetics (PK), pharmacodynamics (PD) and immunogenicity of single and multiple doses of AL003 in healthy volunteers and patients with mild-to-moderate Alzheimer’s disease. In this first-in-human study, AL003 showed a favorable safety and pharmacokinetic profile for once-monthly intravenous dosing. AL003 demonstrated target engagement of CD33 in both blood and central nervous system (CNS) compartments at well tolerated doses.

AL003 is being developed in collaboration with Abbvie. A randomized, controlled Phase 2 trial evaluating AL003 for the treatment of early Alzheimer’s disease is being planned for the second half of 2022.

AL101: Interim Results from a First-in-Human Study
AL101 is a human monoclonal antibody that blocks the sortilin receptor to increase progranulin, a regulator of immune activity in the brain with genetic links to multiple neurodegenerative disorders. The Phase 1 study (NCT04111666) of AL101 enrolled a total of 55 healthy volunteers in six cohorts to test the safety, tolerability, PK, PD and bioavailability of single doses of intravenously or subcutaneously administered AL101.

Study participants were randomized on a 3:8 basis to receive placebo or a single dose of AL101. The majority of the participants received a single IV infusion of AL101 in doses ranging from 6mg/kg to 60mg/kg. Another cohort received 600 mg of AL101 by subcutaneous injection. AL101 was found to be generally safe and well tolerated. The majority of on-study adverse events (AEs) were considered mild to moderate in severity, with the most frequent AEs being headache, anemia and procedural pain. Three serious adverse events were reported, but two were considered unrelated to treatment; the third was indicative of an infusion reaction. AL101 exposure increased in a dose-proportional manner after single ascending intravenous doses. The study also established that AL101 was effectively distributed into the central nervous system, as evidenced by cerebrospinal fluid concentrations of AL101. Further, study results show proof of mechanism for AL101; increases in progranulin levels were observed in the periphery and the brain persisting for one month. Alector is continuing to enroll additional cohorts to test further dosages of AL101 administered intravenously and subcutaneously.

AL101 is being developed under Alector’s collaboration with GlaxoSmithKline (GSK), and the Phase 1 study is ongoing. AL101 is the second of Alector’s progranulin-elevating therapeutic agents and is designed for less frequent dosing.

Data for AL003 and AL101, as well as a trial design poster for the Phase 3 INFRONT-3 clinical trial of AL001, are being presented at CTAD in poster presentations. The posters are available on the CTAD conference website and will be made available on the Investors section of the Alector website

- A Phase 1 Study of AL003 in Healthy Volunteers and Participants with Alzheimer’s Disease (P45)
- A First-in-human Study of the Anti-Sortilin Antibody AL101 (P46)
- Design of INFRONT-3: A Phase 3 Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Efficacy and Safety of AL001 IN FTD-GRN (P71)

About AL003
AL003 targets CD33, or sialic acid binding Ig-like lectin 3 (Siglec-3), a known a genetic risk factor for Alzheimer’s disease. Siglec-3 is an inhibitory receptor expressed primarily on cells of myeloid lineage including microglia, which constitute the brain’s immune system. Mutations or overexpression of CD33 are understood to suppress healthy microglial activity and enable the build-up of toxic proteins, such as beta amyloid. AL003 is a monoclonal antibody that works by decreasing the expression of Siglec-3 to increase the activity of microglia. By inhibiting Siglec-3/CD33 expression, AL003 is intended to reverse inhibition of immune cell activity and restore homeostasis. AL003 is being developed by Alector in collaboration with AbbVie.

About AL101
AL101 is a human monoclonal antibody designed to increase 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, and increased progranulin levels have been demonstrated to be protective for these diseases in animal models.

AL101 received orphan drug designation from the U.S. Food and Drug Administration for the treatment of frontotemporal dementia in July 2019. In July 2021, Alector and GSK announced a global collaboration to co-develop and co-commercialize two progranulin-elevating candidates, AL001 and AL101, for a range of neurodegenerative diseases, including frontotemporal dementia, amyotrophic lateral sclerosis, Parkinson's disease and Alzheimer's disease.

About Alzheimer's Disease
Alzheimer's disease is a degenerative brain disease and the most common form of dementia. It is an irreversible, progressive brain disorder that slowly destroys memory and thinking skills, and eventually the ability of patients to care for themselves. In most people with Alzheimer's disease, symptoms first appear in their mid-60s. The Alzheimer's Association estimates that as of 2020, there are 5.8 million Americans aged 65 and older living with Alzheimer's disease, and projects that number will rise to nearly 14 million by 2050.

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 the rejuvenated immune cells to counteract emerging brain pathologies. Alector's immuno-neurology product candidates are supported by biomarkers and target genetically defined patient populations in frontotemporal dementia and Alzheimer's disease. This scientific approach is also the basis for the company's immuno-oncology programs. 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 market conditions, Alector and its business as set forth in our Quarterly Report on Form 10-Q, as filed on November 4, 2021 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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