Alector Announces Topline Results from Latozinemab Phase 3 Trial in Individuals with Frontotemporal Dementia Due to a GRN Mutation and Provides Business Update

October 21, 2025

SOUTH SAN FRANCISCO, Calif., Oct. 21, 2025 (GLOBE NEWSWIRE) -- Alector, Inc. (Nasdaq: ALEC), a clinical-stage biotechnology company focused on developing therapies to counteract the devastating progression of neurodegeneration, today announced results from the Phase 3 INFRONT-3 clinical trial evaluating latozinemab (AL001) in individuals with frontotemporal dementia due to a progranulin gene mutation (FTD-*GRN*).

In the 96-week, double-blind INFRONT-3 trial, latozinemab, developed in collaboration with GSK, did not meet the clinical co-primary endpoint of slowing FTD-*GRN* progression, as measured by the Clinical Dementia Rating® plus National Alzheimer's Coordinating Center Frontotemporal Lobar Degeneration Sum of Boxes (CDR® plus NACC FTLD-SB). Although treatment resulted in a statistically significant effect on the biomarker co-primary endpoint of plasma progranulin (PGRN) concentrations, the secondary and exploratory endpoints, such as fluid biomarkers and volumetric magnetic resonance imaging (vMRI), demonstrated no treatment-related effects on FTD-*GRN*. Preliminary safety data have not highlighted any major safety concerns at present. More in-depth analysis of the data is ongoing.

"While latozinemab did not demonstrate a clinical benefit in INFRONT-3, the insights gained are invaluable for understanding progranulin-related neurodegeneration," said Giacomo Salvadore, M.D., Chief Medical Officer of Alector. "We extend our deepest gratitude to the patients, caregivers, and investigators who made this trial possible, and we plan to share the results with the scientific community to support continued progress in understanding progranulin biology and FTD pathophysiology."

Based on these results, the open-label extension portion of the INFRONT-3 trial and the continuation study for latozinemab will be discontinued.

The INFRONT-3 trial results will be presented at an upcoming medical congress.

Alector Pipeline Outlook

Alector remains focused on advancing a pipeline of programs designed to treat neurodegenerative diseases through mechanisms that remove toxic proteins, replace deficient proteins, and restore immune and neuronal function.

In the ongoing collaboration with GSK, nivisnebart (AL101/GSK4527226) is being evaluated in PROGRESS-AD, a global, 76-week Phase 2 clinical trial in individuals with early Alzheimer's disease (AD). Enrollment was completed in April 2025, and trial completion is expected in 2026. An independent interim analysis is planned for the first half of 2026.

A key pillar of Alector's focus is its proprietary blood-brain barrier (BBB) technology platform, Alector Brain Carrier (ABC). Built on the core design principles of versatility, tunability, and differentiated binding to a distinct region of the transferrin receptor (TfR), ABC is intended to support the targeted delivery of therapeutics to the brain and to optimize safety and efficacy at lower doses. The platform's tunable TfR binding affinities allow adjustment of binding strength to align with the needs of diverse therapeutic cargos, including antibodies, enzymes, proteins, and siRNA, aiming to achieve efficient transport across the BBB with the goal of balancing brain uptake, potency, and safety.

Alector is progressing multiple preclinical programs enabled by ABC and has selected lead candidate AL137 for its ABC-enabled anti-amyloid beta (Aβ) antibody program in AD, and AL050 for its ABC-enabled glucocerebrosidase (GCase) enzyme replacement therapy program in Parkinson's disease (PD). The company is targeting submission of investigational new drug (IND) applications for AL137 in 2026 and for AL050 in 2027.

Alector is also continuing to advance its ABC-enabled siRNA platform. The platform is being designed for peripheral dosing, offering the potential for more convenient administration compared with traditional intrathecal or intracerebroventricular delivery. The most advanced siRNA program is ADP064-ABC, targeting tau for the potential treatment of AD and FTD.

Collectively, these programs reflect Alector's continued commitment to advancing innovative approaches to treat neurodegenerative diseases.

Alector Executive Leadership and Business Update

To align resources with these strategic priorities, Alector is reducing its workforce by approximately 49%. This is intended to focus the company's resources on its highest-priority programs and to ensure continued progress across its portfolio. Alector thanks all employees affected by these measures for their dedication and contributions to the company's mission.

In parallel, Sara Kenkare-Mitra, Ph.D., President and Head of Research and Development (R&D), has resigned from her role, effective December 22, 2025, to pursue new leadership opportunities. She will remain with Alector until then to ensure a smooth transition and continuity across the R&D organization. The company is deeply appreciative of Dr. Kenkare-Mitra for her leadership and impactful contributions to Alector.

"Sara has been an extraordinary builder and operator who transformed Alector into a mature, fully integrated R&D organization," said Arnon Rosenthal, Ph.D., Chief Executive Officer of Alector. "Her sage leadership has been critical for the successful execution of our preclinical and clinical pipeline programs. Sara's integrity and vision have left a lasting mark on the science, culture, and people at Alector, and we wish her continued success in her next chapter."

Alector estimates that it had approximately $291.1 million in cash, cash equivalents, and short-term investments as of September 30, 2025, which the company expects will provide runway through 2027. Alector plans to issue guidance for 2026 when it reports fourth quarter and full year 2025 financial results.

About INFRONT-3
INFRONT-3 (ClinicalTrials.gov identifier NCT04374136) was a pivotal, randomized, double-blind, placebo-controlled Phase 3 clinical trial evaluating the safety and efficacy of latozinemab (AL001) in slowing disease progression in individuals with frontotemporal dementia due to a progranulin gene mutation (FTD-*GRN*). The trial enrolled symptomatic and at-risk FTD-*GRN* participants at multiple sites across North America, Europe, Argentina, and the Asia-Pacific region. The primary analysis was conducted in symptomatic participants only, in alignment with regulatory guidance from the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA).

Based on the FDA's recommendation, Alector and GSK amended the statistical analysis plan in the U.S. to include plasma progranulin (PGRN) concentration as a co-primary endpoint along with the Clinical Dementia Rating® plus National Alzheimer's Coordinating Center Frontotemporal Lobar Degeneration Sum of Boxes (CDR® plus NACC FTLD-SB). This designation of plasma PGRN as a co-primary endpoint does not apply outside the United States.

Participants were randomized to receive 60 mg/kg of latozinemab or placebo intravenously every four weeks over the 96-week treatment period (Part 1, the double-blind period). Following completion of Part 1, participants could either enter a 10-week safety follow-up or roll over into a 96-week open-label extension (OLE) study. Those who completed the OLE had the option to roll over into a continuation study (ClinicalTrials.gov identifier NCT06111014).

About Alector
Alector is a clinical-stage biotechnology company focused on developing therapies to counteract the devastating progression of neurodegenerative diseases. Leveraging the principles of genetics, immunology, and neuroscience, the company is advancing a portfolio of programs that aim to remove toxic proteins, replace missing proteins, and restore immune and nerve cell function. Supported by biomarkers, Alector's product candidates seek to treat a range of indications, such as Alzheimer's disease, Parkinson's disease, and frontotemporal dementia. The company is also developing Alector Brain Carrier (ABC), a proprietary blood-brain barrier platform, which is being selectively applied to its preclinical and research pipeline. ABC aims to enhance the delivery of therapeutics, achieve deeper brain penetration and efficacy at lower doses, and ultimately improve patient outcomes while reducing costs. Alector is headquartered in South San Francisco, California. For more 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. Forward-looking statements in this press release include, but are not limited to, statements regarding our business plans, business strategy, workforce reduction, product candidates, research and preclinical pipeline, blood-brain barrier technology platform, planned and ongoing preclinical studies and clinical trials, anticipated timing of and detail regarding release of data for PROGRESS-AD, expected milestones, expectations of our collaborations and financial and cash guidance. Such statements are subject to numerous risks and uncertainties, including but not limited to risks and uncertainties as set forth in Alector's Annual Reports on Form 10-K and Quarterly Reports on Form 10-Q, 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.

Alector Contacts:
Alector
Katie Hogan
202-549-0557
katie.hogan@alector.com

Argot Partners (media)
David Rosen
646-461-6387
alector@argotpartners.com

Argot Partners (investors)
Laura Perry
212-600-1902
alector@argotpartners.com

Source: Alector, Inc.