Alector Announces Results from AL002 INVOKE-2 Phase 2 Trial in Individuals with Early Alzheimer's Disease and Provides Business Update

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SOUTH SAN FRANCISCO, Calif., Nov. 25, 2024 (GLOBE NEWSWIRE) -- Alector, Inc. (Nasdaq: ALEC), a clinical-stage biotechnology company pioneering novel, genetically validated therapies for the treatment of neurodegenerative diseases, today announced results from the INVOKE-2 Phase 2 clinical trial evaluating the safety and efficacy of AL002 in slowing disease progression in individuals with early Alzheimer's disease (AD). Treatment with AL002 resulted in sustained target engagement and pharmacodynamic responses indicative of microglial activation. However, AL002 failed to meet the primary endpoint of slowing of Alzheimer's clinical progression as measured by the Clinical Dementia Rating Sum of Boxes (CDR ®-SB), and there were no treatment effects that favored AL002 on secondary clinical and functional endpoints. Similarly, there were no significant effects on Alzheimer's fluid biomarkers favoring AL002, and amyloid PET imaging demonstrated no treatment-related reduction of brain amyloid levels. As previously reported, MRI changes resembling amyloid-related imaging abnormalities (ARIA) and infusion-related reactions were observed in INVOKE-2. The instances of ARIA were primarily seen in participants treated with AL002.

"We, at Alector, recognize the importance of advancing therapeutics to treat Alzheimer's disease and remain committed in our mission to develop safe and effective treatments for the millions of people worldwide impacted by neurodegenerative diseases," said Gary Romano, M.D., Ph.D., Chief Medical Officer at Alector. "With a robust dataset from the INVOKE-2 trial, we plan to further explore TREM2 biology. We extend our deepest gratitude to the dedicated investigators, patients and caregivers who made this important trial possible. We plan to share the results of the trial with the scientific community in the near future in the hopes of contributing to the understanding of AD pathophysiology and advancing effective therapeutics for this terrible disease."

Based upon the results, Alector is stopping the long-term extension study.

Alector remains committed to advancing its mechanistically broad and genetically validated drug candidates for the treatment of neurodegenerative diseases. At the core of this effort are the company's progranulin-elevating programs, latozinemab and AL101/GSK4527226, developed in collaboration with GSK. Topline data from the pivotal INFRONT-3 Phase 3 clinical trial of latozinemab in frontotemporal dementia with a progranulin gene mutation is expected in late 2025 or early 2026. PROGRESS-AD, a global Phase 2 clinical trial evaluating AL101/GSK4527226 in early AD, has reached more than one-third of its target enrollment of 282 participants. Alector is also advancing its preclinical candidates aimed at a broad and diverse range of protein and enzyme targets.

In addition to advancing its pipeline, the company is continuing to develop its proprietary and versatile blood-brain barrier technology platform, Alector Brain Carrier (ABC). ABC aims to enhance the delivery of therapeutic antibodies, proteins and enzymes, achieve deeper penetration and efficacy at lower doses, and ultimately improve patient outcomes while reducing costs.

To align resources with these strategic priorities, Alector is reducing its workforce by approximately 17%. By focusing on organizational goals, Alector continues to build upon its core strength in developing novel therapies for neurodegenerative diseases, with the potential to deliver transformative value for patients.

As of September 30, 2024, Alector has $457.2 million in cash, cash equivalents, and investments, which the company continues to expect will provide runway through 2026. Alector plans to provide guidance for 2025 during its fourth-quarter and full-year earnings conference call.

About INVOKE-2
INVOKE-2 (Clinicaltrials.gov identifier NCT04592874), was a randomized, double-blind, placebo-controlled, dose-ranging, multi-center Phase 2 clinical trial evaluating the safety and efficacy of AL002 in slowing disease progression in individuals with early Alzheimer's disease (AD). The trial, conducted at multiple sites across 11 countries, utilized a common close design with up to 96 weeks of randomized treatment, and all participants remained on their assigned regimen until the last participant completed 48 weeks of treatment. This design provided the opportunity to capture more observations for the primary analysis, with data collected at 48, 72, and 96 weeks. Patients were randomized to three dose regimens of AL002, 15mg/kg IV/q4w, 40mg/kg IV/q4w, 60mg/kg IV/q4w, or placebo.

About Alector
Alector is a clinical-stage biotechnology company that has pioneered immuno-neurology. The company has discovered and is developing a portfolio of mechanistically broad and genetically validated product candidates, including antibodies, protein and enzyme replacement therapies, for neurodegenerative diseases. Supported by biomarkers, Alector's product candidates seek to treat a range of indications, including frontotemporal dementia, Alzheimer's disease, and Parkinson's disease. Alector is also developing Alector Brain Carrier (ABC), a proprietary blood-brain barrier platform, which is being selectively applied to its next-generation product candidates and research pipeline. ABC aims to enhance the delivery of therapeutics, achieve deeper 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, workforce reduction, business strategy, product candidates, planned and ongoing preclinical studies and clinical trials, expected milestones, and expectations of our collaborations. Such statements are subject to numerous risks and uncertainties, including but not limited to risks and uncertainties as set forth in Alector's Quarterly Report on Form 10-Q filed on November 6, 2024, 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

1AB (media)
Dan Budwick
973-271-6085
dan@1abmedia.com

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

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