Lilly's Quest for Alzheimer's Disease Treatment

With more than three decades of commitment to research in Alzheimer's disease (AD) and a robust diagnostic and treatment pipeline, Lilly remains dedicated to bringing Alzheimer's disease treatments to patients in need.

We are grateful to the study participants, care partners and investigators who make this research possible.

Key Clinical Trials

Lilly's TRAILBLAZER program is made up of six clinical studies.

These trials evaluate the safety and efficacy of donanemab.*

TRIAL NAME	STAGE OF ALZHEIMER'S DISEASE	DRUG	PHASE	TRIAL TYPE	TRIAL GOAL(S)	PARTICIPANTS	# OF PARTICIPANTS (estimated)	LOCATION
TRAILBLAZER-ALZ	Early symptomatic (MCI or mild dementia)	Donanemab vs. placebo	Phase 2	Randomized, double-blind, placebo-controlled	Evaluate the safety, tolerability and efficacy of donanemab in patients with early symptomatic AD with the presence of low-medium tau pathology	Adults aged 60-85 with early symptomatic AD who meet entry criteria including a Mini-Mental State Examination (MMSE) score of 20-28, gradual and progressive change in memory function for more than six months, and the presence of both amyloid plaque and low-medium tau pathology as determined from a PET scan, among other criteria	272	U.S. and Canada
TRAILBLAZER-ALZ2	Early symptomatic (MCI or mild dementia)	Donanemab vs. placebo	Phase 3	Randomized, double-blind, placebo-controlled	Evaluate the safety and efficacy of donanemab in patients with early symptomatic AD with the presence of brain tau pathology	Adults aged 60-85 with early symptomatic AD who meet entry criteria including a MMSE score of 20-28, gradual and progressive change in memory function for more than six months, and the presence of both amyloid plaque and brain tau pathology as determined from a PET scan, among other criteria	1,736	U.S., Canada, Japan, E.U., UK, Australia
TRAILBLAZER-ALZ3	Preclinical	Donamemab vs. placebo	Phase 3	Randomized, double-blind, placebo-controlled	Evaluate the safety and efficacy of donanemab in patients with preclinical AD	Adults aged 55-80 who have amyloid and early-tau pathology, but who present as cognitively unimpaired	2,600	U.S., Japan
TRAILBLAZER-ALZ4	Early symptomatic (MCI or mild dementia)	Donanemab vs. aducanumab	Phase 3	Randomized, open-label trial with active comparator	Evaluate amyloid plaque clearance with donanemab compared with aducanumab	Adults aged 50-85 with early symptomatic AD who meet entry criteria including a Clinical Dementia Rating (CDR)-Global Score of 0.5 or 1 and gradual and progressive change in memory function for more than six months, among other criteria	148	U.S.
TRAILBLAZER-ALZ5	Early symptomatic (MCI or mild dementia)	Donanemab vs. placebo	Phase 3	Randomized, double-blind, placebo-controlled	Evaluate the safety and efficacy of donanemab in patients with early symptomatic AD with the presence of brain tau pathology	Adults aged 60-85 with early symptomatic AD who meet entry criteria including a MMSE score of 20-28, gradual and progressive change in memory function for more than six months, and the presence of both amyloid plaque and brain tau pathology as determined from a PET scan, among other criteria	1,500	China, Korea, Taiwan, U.K., E.U.
TRAILBLAZER-ALZ6	Early symptomatic (MCI or mild dementia)	Donanemab vs. placebo	Phase 3b	Randomized, double-blind	Explore participant characteristics that might predict risk of ARIA and investigate different donanemab dosing regimens and their effect on the frequency and severity of ARIA-E in adults with early symptomatic AD	Adults aged 60-85 with early symptomatic AD who meet entry criteria including a MMSE score of 20-28, gradual and progressive change in memory function for more than six months, and the presence of both amyloid plaque and brain tau pathology as determined from a PET scan, among other criteria	800	U.S. and U.K.

Visit LillyAlzheimersTrials.com for additional information on enrolling in AD trials.

*Donanemab is an investigational agent currently under review by the FDA for the treatment of early symptomatic Alzheimer's disease. This is a forward-looking planning document and there is no guarantee that donanemab will receive regulatory approval and become commercially available for the uses being investigated. It is not our intention to implement marketing or promotional communications prior to regulatory approval of anticipated approved indications. Subject to local review and approval, any marketing or promotional activities will be developed/implemented consistent with an applicable approved label and carried out in compliance with all company policies and applicable laws and regulations.

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