ALZ-101 Phase 1b clinical study in patients with Alzheimer's disease



Study: Double-blind, randomized, placebo-controlled study on safety, tolerability and immunogenicity.

Part A - ALZ-101 (125 and 250 μg) or placebo, give n at weeks 0, 4, 8 and 16, if not eligible for Part B, follow-up for additional 48 weeks

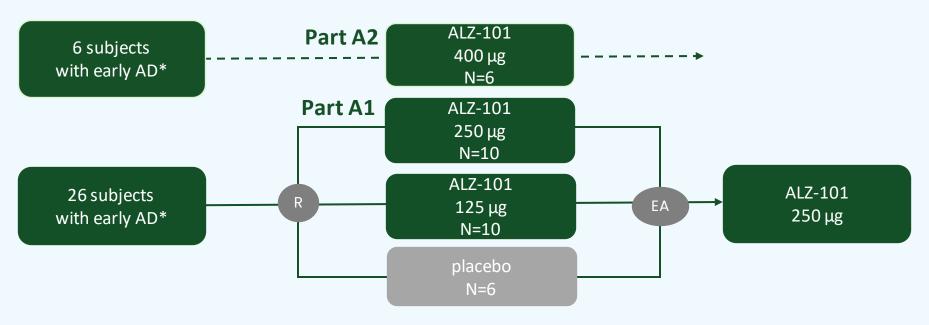
Part A2 - ALZ-101 (400 µg), given at weeks 0, 4, 8 and 16, follow up 4 weeks

Part B - ALZ-101 (250 µg), given at week 0, 4, 8 and 16 and for additional 48 weeks

Patient population: Patients between 50-80 years, MCI due to AD or mild AD*, CSF pattern consistent with amyloid plaque load and indicative of AD pathology.

Endpoints:

Primary; Safety, tolerability - Secondary: Immunogenicity (Αβ-specific) - Exploratory: Biomarkers (CSF & blood) and cognition



*according to National Institute of Aging – Alzheimer's Association (NIA-AA)
MCI – Mild Cognitive Impairment; AD – Alzheimer's Disease; CSF – Cerebrospinal fluid; Aβ – a myloid-beta