Alzheimer Europe

*Making dementia a priority:*
*changing perceptions, practice and policy.*

# CLINICAL TRIALS WATCH

## ACCESSIBLE EASY READ INFORMATION ON:

# INVOKE-2 STUDY

**Alzheimer Europe A.S.B.L.** • R.C.S. Luxembourg F2773 • 14, rue Dicks • L-1417 Luxembourg
Tel.: +352-29 79 70 • Fax: +352-29 79 72 • info@alzheimer-europe.org • www.alzheimer-europe.org

# INVOKE-2 study

| 1. Study Information | |
|---|---|
| **Name of the study** | A Phase 2 study to evaluate efficacy and safety of AL002 in rarticipants with early Alzheimer's disease |
| **Study sponsor** | Alector Inc. |
| **Disease** | Early Alzheimer's disease |
| **Phase** | Phase II |

| 2. Information about the drug that will be tested in the study | |
|---|---|
| **Name of drug** | AL002 |
| **Administration** | The drug will be administered via an intravenous infusion (an injection into the vein) every four weeks. |
| **Is the drug already on the market for another medical condition?** | No |
| **Will all participants receive the same drug?** | Participants will be selected at random to either receive one of the following options:<br>• An intravenous infusion of AL002<br>• An intravenous infusion of placebo (a substance which looks like the trial drug but has no study drug in it).<br><br>Neither the participant nor his/her doctor will know if the person is receiving the investigational drug or the placebo. |

| 3. Information about participating in the trial | |
|---|---|
| **What are the researchers trying to find out?** | • The purpose of the study is to evaluate the safety and efficacy of AL002 in participants with early Alzheimer's disease. |
| **How long will the treatment last?** | • Up to 2 years |
| **What your involvement will entail?** | • Complete a test that will assess memory, orientation, judgment and problem solving, personal care and community affairs (this is a test called CDR) |

| | |
|---|---|
| | • During the study, participants will be asked to complete tests that will assess their functioning, cognition improvement and activities of daily living (i.e. tests like ADAS-Cog13 and RBANS)<br><br>• Participants will be asked to undertake brain scans (MRI) and optional lumbar punctures (CSF) to see changes in biomarkers in the brain<br><br>• Complete some laboratory tests to evaluate the emergent adverse effects (unfavourable signs, symptoms or diseases temporally associated with the use of the drug tested in the study).<br><br>Further information on the number of visits can be obtained from the study team. |

| **4. Who can participate in this study?** | |
|---|---|
| **Who can participate in the study?** | To take part in the study, participants must:<br><br>• Be 50 to 85 years old<br><br>• Have a diagnosis of early Alzheimer's disease including by an appropriately qualified medical specialist (as per results of CSF examination (spinal tap) or amyloid PET scan)<br><br>• Have a score of 0.5 to 1 in the Clinical Dementia Rating-Global Score (CDR) and a score of 22 or above in the MMSE test questionnaire test (a test about your memory). This would suggest that the person has an impairment in their memory that is at a very mild stage.<br><br>• Have a study partner who has a sufficient contact with the participant, is willing to participate in study procedures throughout the study duration (at least 10 hours a week). |
| **Who cannot participate in the study?** | Exclusion criteria include: |

| | |
|---|---|
| | • Any other type of dementia that is not Alzheimer's disease (i.e. Parkinson's disease, dementia with Lewy bodies, Huntington disease, or vascular dementia)<br>• History or evidence of clinically significant brain disease other than AD<br>• History of severe allergic or hypersensitivity reactions to humanised antibodies<br>• Have a progressive medical condition that in the opinion of the investigator would interfere with the conduct of the study (i.e. uncontrolled hypertension, diabetes, heart disease, kidney disease)<br>• A pregnancy or breast-feeding for female participants<br>• History of unresolved cancer<br>• Residence in a nursing facility, convalescent home or long-term care facility.<br><br>The above list is not exhaustive. It includes the most common conditions and diseases that might exclude people from the study. |

| **5. Where and when will the study be conducted?** | |
|---|---|
| **European countries involved in the trial** | • Italy<br>• Netherlands<br>• Poland<br>• Spain<br>• France<br>• Germany<br>• UK |
| **Estimated start date of recruitment** | January 2021 |

| 6. Information for your doctor | | | |
|---|---|---|---|
| **EudraCT Number**: | 2019-001476-11 | **Clinicaltrials.gov identifier** | NCT04592874 |
| **Study contact information** | clinicaltrials@alector.com | | |
| **Link to full text** | https://clinicaltrials.gov/ct2/show/NCT04592874 | | |

- ✓ The information contained in this document is based on information available on public registries (e.g. clinicaltrials.gov website) on May 2021.
- ✓ This document has been reviewed by the pharmaceutical company running this trial.
- ✓ This document has been reviewed by a member of the European Working Group of People with Dementia.