Alzheimer Europe

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changing perceptions, practice and policy.

CLINICAL TRIALS WATCH

ACCESSIBLE EASY READ INFORMATION ON:

INFRONT-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

INFRONT-2 study

1. Study Information	
Name of the study	A Phase 2 Study to Evaluate Safety of Long-term AL001 Dosing in Frontotemporal Dementia (FTD) Patients (INFRONT-2)
Study sponsor	Alector Inc.
Disease	Frontotemporal dementia
Phase	Phase II

2. Information about the drug that will be tested in the study	
Name of drug	AL001
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?	All participants will receive an intravenous infusion of AL001.

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 AL001 in participants at risk for or with frontotemporal dementia due to mutations in the progranulin or C9orf72 genes.
How long will the treatment last?	• 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® plus NACC FTLD-SB) • During the study, participants will be asked to complete tests that will assess their functioning, cognition and improvement (i.e. tests like CGI-S, FRS and RBANS)

	• Participants will be asked to undertake brain scans (MRI) and optional lumbar punctures (CSF) to see changes in biomarkers in the brain • 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). 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: • Be 18 to 85 years old • Have a progranulin gene mutation or a mutation of the C9orf72 gene (a mutation in one of these genes is a major genetic cause of frontotemporal dementia) • Be in good physical health based on no clinically significant findings from medical history, physical examinations, laboratory tests and electrocardiograms (electrical activity of your heart) • Female participants must be nonpregnant and nonlactating.
Who cannot participate in the study?	Exclusion criteria include: • History of severe allergic or hypersensitivity reactions to humanised antibodies • History of alcohol abuse or substance abuse • Residence in a nursing facility, convalescent home or long-term care facility.

	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	• Germany • Italy • Netherlands • UK
Estimated start date of recruitment	September 2019

6. Information for your doctor			
EudraCT Number:	2019-000138-20	**Clinicaltrials. gov identifier**	NCT03987295
Study contact information	clinicaltrials@alector.com		
Link to full text	https://www.clinicaltrials.gov/ct2/show/NCT03987295		

- ✓ 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.