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CLINICAL TRIALS WATCH

ACCESSIBLE EASY READ INFORMATION ON:

INFRONT-3 STUDY

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INFRONT-3 study

1. Study Information	
Name of the study	A Phase 3 study to evaluate efficacy and safety of AL001 in frontotemporal dementia (INFRONT-3)
Study sponsor	Alector Inc.
Disease	Frontotemporal dementia
Phase	Phase III

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?	Participants will be selected by chance to receive one of the following options: • An intravenous infusion of AL001 • An intravenous infusion of placebo (a substance which looks like the trial drug but has no study drug in it). Neither the participant nor their 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 AL001 in participants at risk for or with frontotemporal dementia due to heterozygous mutations in the progranulin gene.
How long will the treatment last?	• 1- 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 25 to 85 years old • Have a progranulin gene mutation (a mutation in the gene called progranulin is a major genetic cause of frontotemporal dementia) • Be at risk of developing frontotemporal dementia symptoms as evidenced by a biomarker, or people diagnosed with frontotemporal dementia • Have a study partner who has a sufficient contact with the participant (at least 5 hours per week) is willing to participate in study procedures throughout the study duration.
Who cannot participate in the study?	Exclusion criteria include: • Participant who have dementia due to a condition other than frontotemporal dementia (i.e. Alzheimer's disease,

	Parkinson's disease, dementia with Lewy bodies, Huntington disease, or vascular dementia) • History of severe allergic or hypersensitivity reactions to humanised antibodies • 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) • A pregnancy or lactation for female participants • 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 (active)	• Belgium • France • Germany • Greece • Italy • Netherlands • Portugal • Spain • Sweden • Switzerland • Turkey • UK
Estimated start date of recruitment	July 2020

6. Information for your doctor			
EudraCT Number:	2019-004066-18	**Clinicaltrials.gov identifier**	NCT04374136
Study contact information	clinicaltrials@alector.com		
Link to full text	https://www.clinicaltrials.gov/ct2/show/NCT04374136		
For further information	https://www.health-panel.com/research-projects/research-study-for-adults-with-frontotemporal-dementia/?cl=pag-48		

- ✓ The information contained in this document is based on information available on public registries (e.g. clinicaltrials.gov website) on April 2023.
- ✓ 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.