Alzheimer Europe

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changing perceptions, practice and policy.

CLINICAL TRIALS WATCH

ACCESSIBLE EASY READ INFORMATION ON:

DNLI-H-0001 STUDY

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DNLI-H-0001 study

1. Study Information	
Name of the study	A study to evaluate the safety, tolerability, pharmacokinetics, and pharmacodynamics of DNL593 in healthy participants and participants with Frontotemporal Dementia (FTD-GRN)
Study sponsor	Denali Therapeutics Inc.
Disease	Frontotemporal Dementia (FTD)
Phase	Phase I/II

2. Information about the drug that will be tested in the study	
Name of drug	DNL593
Administration	The drug will be administered via an intravenous infusion (an injection into the vein).
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 DNL593 • An intravenous infusion of placebo (also called a dummy treatment which is an inactive substance identical in appearance to the drug being tested with no active therapeutic effect) for 24 weeks. Healthy participants will receive ascending single doses of either DNL593 or placebo. Participants with Frontotemporal Dementia will receive multiple doses of either DNL593 or placebo. 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, tolerability, pharmacokinetics, and pharmacodynamics of DNL593 in

	healthy participants and participants with Frontotemporal Dementia.
How long will the treatment last?	• The treatment lasts 25 weeks • Participants with Frontotemporal Dementia who will complete the trial will be eligible to enter an optional 18-month open-label extension period.
What your involvement will entail?	• During the study, participants will be asked to complete some laboratory and biological tests to evaluate the emergent adverse effects (unfavourable signs, symptoms or diseases temporally associated with the use of the drug tested in the study) • Participants will complete some other tests to measure blood pressure, heart rate and heart's rhythm (ECG) • Participants will be asked to perform lumbar punctures (CSF) to see changes in biomarkers in the brain • Complete a questionnaire about the suicidal ideation and behaviour (this is a test called Columbia-Suicide Severity Rating Scale - C-SSRS). Further information on the procedures, tests and 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, all participants must: • Be between 18 and 80 years old • Have a body mass index (BMI) of ≥ 18 to ≤ 32 kg/m² • Use highly effective contraception • Women of non-childbearing potential (surgically sterilized or post-menopausal).

	To take part in the study, participants with Frontotemporal Dementia must: • Have a score of ≥ 0.5 in the Clinical Dementia Rating® plus National Alzheimer's Coordinating Center frontotemporal lobar degeneration global score • Have confirmed granulin (GRN) mutation via genetic testing or historical records available.
Who cannot participate in the study?	Exclusion criteria include: • Presence of other significant neurological or psychiatric disorders • History of malignancy • History of stroke, cognitive impairment due to causes other than Frontotemporal Dementia • Have a positive serum pregnancy test or are currently lactating or breastfeeding. 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	• Spain • UK
Estimated start date of recruitment	February 2022

6. Information for your doctor			
EudraCT Number	2021-005733-16	**Clinicaltrials.gov identifier**	NCT05262023
Study contact information	Enrolmentservices@simbecorion.com		
Link to full text	https://clinicaltrials.gov/ct2/show/NCT05262023		

- ✓ The information contained in this document is based on information available on public registries (e.g. clinicaltrials.gov website) on November 2022.