Alzheimer Europe

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

CLINICAL TRIALS WATCH

ACCESSIBLE EASY READ INFORMATION ON:

GAIN Trial

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GAIN Trial

1. Study Information	
Name of the study	GAIN (GingipAIN Inhibitor for Treatment of Alzheimer's Disease)
Study sponsor	Cortexyme Inc.
Disease	Mild to moderate Alzheimer's disease dementia
Phase	Phase II/III

2. Information about the drug that will be tested in the study	
Name of drug	COR388
Administration	A capsule taken orally two times a day
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 three options: • A capsule of 40mg of COR388 • A capsule of 80mg of COR388 • A placebo capsule (also called a dummy treatment which is an inactive substance identical in appearance to the drug being tested). 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 and effectiveness of two doses of COR388 oral capsules in subjects with Alzheimer's disease dementia.
How long will the treatment last?	• 48 weeks with 6 weeks safety follow up.
What your involvement will entail?	• During the study, participants will undergo brain imaging, blood work, a physical exam, lumbar puncture, medical history and possibly oral exam. scan (MRI) and CSF examination (spinal tap)

	• Complete a test that will assess their memory, orientation, judgment and problem solving, personal care and community affairs • Participants will be asked to complete other tests that will assess their memory, language, functioning, behaviour, quality of life and other health-related questionnaires

4. Who can participate in this study?	
Who can participate in the study?	To take part in the study, participants must: • Be between 55 and 80 years old • Have been diagnosed with mild to moderate Alzheimer's disease. • Be willing to have a study partner who will attend study visits, report on daily activities and oversee taking the medication.
Who cannot participate in the study?	Exclusion criteria include: • Dementia or other memory impairment not due to Alzheimer's disease • A medical or neurological condition or laboratory results that may interfere with the study (e.g. schizophrenia, psychiatric disorders, poorly controlled diabetes, HIV, Hepatitis). 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	• France • Netherlands • Poland • Spain • UK

Estimated start date of recruitment	September 2019

6. Information for your doctor			
EudraCT Number:	2019-000370-27	**Clinicaltrials.gov identifier**	NCT03823404
Study contact information	clinicaltrials@cortexyme.com annette.janus@worldwide.com		
Link to full text	https://clinicaltrials.gov/ct2/show/study/NCT03823404		

- ✓ The information contained in this document is based on information available on public registries (e.g. clinicaltrials.gov website) on February 2020.
- ✓ 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.