Alzheimer Europe

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CLINICAL TRIALS WATCH

ACCESSIBLE EASY READ INFORMATION ON:

Brexpiprazole 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

Brexpiprazole study

1. Study Information	
Name of the study	A trial to evaluate the safety, efficacy, and tolerability of Brexpiprazole in treating agitation associated with dementia of the Alzheimer's type
Study sponsor	Otsuka Pharmaceutical Development & Commercialization, Inc.
Disease	Agitation in people with dementia of the Alzheimer's type
Phase	Phase III

2. Information about the drug that will be tested in the study	
Name of drug	Brexpiprazole (also called OPC-34712)
Administration	A tablet taken orally
Is the drug already on the market for another medical condition?	Yes. Brexpiprazole (REXULTI®) is a molecule approved as an adjunctive therapy to antidepressants in adults with major depressive disorder (US) and as a treatment in adults with schizophrenia (US, EU).
Will all participants receive the same drug?	Participants will be selected at random to either receive one of the following options: • A tablet of low dose of Brexpiprazole • A tablet of high dose of Brexpiprazole • One placebo tablet (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 efficacy, safety and tolerability of two doses of Brexpiprazole in the treatment of

	people with agitation associated with dementia of the Alzheimer's type.
How long will the treatment last?	• 12 weeks
What your involvement will entail?	• Participants will be requested to complete a memory test (MMSE) • Participants will be also asked to complete two questionnaires that will assess the frequency of agitated behaviours (this is a test called CMAI) and the severity of agitation (CGI-S). Further information on the procedures, tests and 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 between 55 and 90 years old • Have a diagnosis of probable Alzheimer's disease • Have a diagnosis of agitation • Be willing to complete a memory test (MMSE). To be able to participate, the score of this test should suggest that the participant has a cognitive impairment that is mild, moderate or severe (i.e. score between 5-22). • Have results of a brain scan (MRI or CT) that was performed after the onset of symptoms of dementia, with findings consistent with a diagnosis of Alzheimer's disease • Be willing to have a study partner who has a sufficient contact with the participant (minimum of 2 hours per day for 4 days per week), is willing to accompany the participant to

	the study visits and provides the necessary information about the participant's symptoms and behaviour.
Who cannot participate in the study?	Exclusion criteria include: • Dementia or other memory impairment not due to Alzheimer's disease • History of a stroke, ischemic attack, or pulmonary or cerebral embolism • Diagnosis of Axis I disorders (clinical conditions that are psychological, except personality disorders and mental retardation, such as anxiety disorders, cognitive disorders, mood disorders and schizophrenia) • Uncontrolled hypertension or symptomatic hypotension, or orthostatic hypotension • A medical or neurological condition that may interfere with the study (e.g. neurological hepatic, renal, metabolic, hematological, immunological, cardiovascular, pulmonary, gastrointestinal, or psychiatric disorders). 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	• Bulgaria • Serbia • Spain • Ukraine
Estimated start date of recruitment	May 2018

6. Information for your doctor			
EudraCT Number:	2017-003940-19	**Clinicaltrials. gov identifier**	NCT03548584
Study contact information	medical.information@otsuka-europe.com		
Link to full text	https://clinicaltrials.gov/ct2/show/NCT03548584		

- ✓ The information contained in this document is based on information available on public registries (e.g. clinicaltrials.gov website) on July 2019.
- ✓ This document has not 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.