Alzheimer Europe

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

CLINICAL TRIALS WATCH

ACCESSIBLE EASY READ INFORMATION ON:

17-AVP-786-305 STUDY

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17-AVP-786-305 study

1. Study Information	
Name of the study	A Phase 3, multicenter, randomized, double-blind, placebo-controlled, parallel-design study to assess the efficacy, safety, and tolerability of AVP-786 (deudextromethorphan hydrobromide [d6-DM]/quinidine sulfate [Q]) for the treatment of agitation in patients 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	AVP-786
Administration	A capsule taken orally twice 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 options: • A capsule of AVP-786 administered twice daily (dose 1) • A capsule of AVP-786 administered twice daily (dose 2) • One placebo capsule (also called a dummy treatment which is an inactive substance identical in appearance to the drug being tested with no active therapeutic effect) administered twice daily. Neither the participant nor his/her 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 this study is to evaluate the safety and efficacy of AVP-786 for the treatment of agitation in people with dementia of the Alzheimer's type
How long will the treatment last?	• 12 weeks

What your involvement will entail?	• During the study, participants (and/or their caregivers) will be asked to complete different tests that will assess the participants' behaviour, functioning, quality of life, cognition and the level of burden on the caregiver. 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, participants must: • Be between 50 and 90 years old • Have a diagnosis of Alzheimer's disease and have moderate or severe agitation • Have agitation symptoms that interferes with daily routine • Have a caregiver who is willing and able to comply with study procedures. The caregiver should spend at least 2 hours per day for 4 days per week with the participant.
Who cannot participate in the study?	People cannot take part in the study if they have or have experienced: • Any medical or neurological condition (other than Alzheimer's disease) that might be a contributing cause of the dementia or agitation • A disease that may interfere with the safety or study assessments (e.g., malignancy, poorly controlled diabetes, uncontrolled hypertension, unstable pulmonary, renal or hepatic disease, uncontrolled or significant cardiac disease) • Myasthenia gravis (neuromuscular disease that causes weakness in the skeletal muscles).

	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 • Czech Republic • France • Hungary • Italy • Poland • Spain • UK
Estimated start date of recruitment	May 2018

6. Information for your doctor			
EudraCT Number	2017-001339-38	**Clinicaltrials.gov identifier**	NCT03393520
Study contact information	clinicaldevelopment@otsuka-us.com		
Link to full text	https://clinicaltrials.gov/ct2/show/study/NCT03393520		

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