Alzheimer Europe

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

# CLINICAL TRIALS WATCH

## ACCESSIBLE EASY READ INFORMATION ON:

# 20-AVP-786-306 STUDY

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# 20-AVP-786-306 study

| 1. Study Information | |
|---|---|
| **Name of the study** | Assessment of the efficacy, safety, and tolerability of AVP-786 for the treatment of agitation in patients with dementia of the Alzheimer's type |
| **Study sponsor** | Otsuka Pharmaceutical Development & Commercialization, Inc |
| **Disease** | Dementia of the Alzheimer's Type |
| **Phase** | Phase III |

| 2. Information about the drug that will be tested in the study | |
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| **Name of drug** | AVP-786 |
| **Administration** | Oral capsules twice daily |
| **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:<br>• An oral capsule of AVP-786 twice daily<br>• An oral capsule of placebo (inactive substance identical in appearance to the drug being tested) twice daily.<br><br>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 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 will be asked to complete tests that will assess their agitation (i.e. tests like CMAI and CGI-S).<br><br>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:<br>• Be 50 to 90 years old<br>• Have a diagnosis of probable Alzheimer's disease according to the 2011 Neuropsychiatric Inventory Agitation/Aggression (NPI-AA) working groups criteria<br>• Participant with clinically significant, moderate-to-severe agitation that interferes with daily routine<br>• Diagnosis of agitation must meet the International Psychogeriatric Association (IPA) provisional definition of agitation<br>• Have a study partner who has a sufficient contact with the participant is willing to participate in study procedures throughout the study duration (i.e., study partner who spends a minimum of 2 hours per day for 4 days per week with the participant). |
| **Who cannot participate in the study?** | Exclusion criteria include:<br>• Participant with dementia predominantly of the non-Alzheimer's type (e.g., vascular dementia, frontotemporal dementia, Parkinson's disease, substance-induced dementia)<br>• Participant with symptoms of agitation that are not secondary to Alzheimer's dementia (e.g., secondary to pain, other psychiatric disorder, or delirium)<br>• Participant with unstable systemic diseases or conditions that in the opinion of the investigator would interfere with the conduct of the study (e.g., poorly controlled diabetes, poorly controlled hypertension, unstable pulmonary, renal or hepatic disease, unstable ischemic cardiac disease) |

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| | • Participant with myasthenia gravis (this is a long-term neuromuscular disease).<br><br>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** | • Denmark<br>• Estonia<br>• Germany<br>• Greece<br>• Poland<br>• Portugal<br>• UK |
| **Estimated start date of recruitment** | July 2020 |

| **6. Information for your doctor** | | | |
|---|---|---|---|
| **EudraCT Number**: | 2020-000798-26 | **Clinicaltrials.gov identifier** | NCT04408755 |
| **Study contact information** | clinicaldevelopment@otsuka-us.com | | |
| **Link to full text** | https://clinicaltrials.gov/ct2/show/NCT04408755 | | |

✓ The information contained in this document is based on information available on public registries (e.g. clinicaltrials.gov website) on April 2024.