Alzheimer Europe

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

# CLINICAL TRIALS WATCH

ACCESSIBLE EASY READ INFORMATION ON:

## 15-AVP-786-303
## Extension STUDY

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# 15-AVP-786-303 Extension study

| 1. Study Information | |
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| **Name of the study** | Long term, extension study of the safety and efficacy 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 - Extension study<br>Only participants who have successfully completed previous Phase III studies with AVP-786 can be enrolled (15-AVP-786-301, 15-AVP-786-302, 12-AVR-131, or 17-AVP-786-305). |

| 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 (dose 1)<br>• An oral capsule of AVP-786 twice daily (dose 2)<br>• An oral capsule of AVP-786 twice daily (dose 3)<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 | |
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| **What are the researchers trying to find out?** | • The purpose of the study is to evaluate the efficacy and 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?** | • 52 weeks |
| **What your involvement will entail?** | • During the study, participants will be asked to complete some laboratory tests (e.g. blood test, ECG) to evaluate the side |

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| | effects (it refers to unfavourable signs, symptoms or diseases temporally associated with the use of the drug tested in the study)<br><br>• Participants will also need to complete some other tests to evaluate their cognition, thinking skills, behaviour, agitation and quality of life (e.g. MMSE, CMAI, NPI, DEMQOL)<br><br>• Complete questionnaires to measure the general level of daytime sleepiness (ESS) and access/monitor over time the core phenomena of suicidality (S-STS).<br><br>Further information on the number of visits can be obtained from the study team. |

| **4. Who can participate in this study?** | |
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| **Who can participate in the study?** | To take part in the study, participants must:<br><br>• Be 50 to 90 years old<br>• Have successfully completed previous studies with the drug: 15-AVP-786-301, 15-AVP-786-302, 12-AVR-131, or 17-AVP-786-305<br>• Have a diagnosis of probable Alzheimer's disease according to the 2011 Neuropsychiatric Inventory Agitation/Aggression (NPI-AA) working groups criteria<br>• Either out-patients or residents of an assisted-living facility or a skilled nursing home<br>• Have a diagnosis of agitation according to the International Psychogeriatric Association (IPA) provisional definition of agitation<br>• Have a Clinical Global Impression of Severity of Illness (CGIS) score assessing Agitation of ≥ 4 (moderately ill) at screening and baseline<br>• Have a Mini-Mental State Examination (MMSE) score between 6 and 26 (inclusive) at screening and baseline. |

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| **Who cannot participate in the study?** | Exclusion criteria include:<br>• A disease or a condition that may interfere with the safety or study assessments (e.g. malignancy, poorly controlled diabetes, poorly controlled hypertension, unstable pulmonary, renal or hepatic disease, unstable ischemic cardiac disease, dilated cardiomyopathy, or unstable valvular heart disease)<br>• A high imminent risk of falls during the study based on a clinical evaluation by the investigator<br>• Ongoing use or past use of NUEDEXTA® in the 2 weeks preceding baseline.<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?** | |
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| **European countries involved in the trial** | • Bulgaria<br>• Czechia<br>• France<br>• Hungary<br>• Italy<br>• Poland<br>• Spain |
| **Estimated start date of recruitment** | December 2015 |

| **6. Information for your doctor** | | | |
|---|---|---|---|
| **EudraCT Number**: | 2017-002455-29 | **Clinicaltrials.gov identifier** | NCT02446132 |
| **Study contact information** | smb_clinicaltranspa@otsuka-us.com | | |
| **Link to full text** | https://clinicaltrials.gov/ct2/show/NCT02446132 | | |

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