Alzheimer Europe

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

# CLINICAL TRIALS WATCH

## ACCESSIBLE EASY READ INFORMATION ON:

# VIVIAD STUDY

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# VIVIAD study

| 1. Study Information | |
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| **Name of the study** | A study to evaluate safety and tolerability of different doses and efficacy of PQ912 in subjects with mild cognitive impairment and mild Alzheimer's disease |
| **Study sponsor** | Vivoryon Therapeutics AG |
| **Disease** | Alzheimer's disease |
| **Phase** | Phase IIb |

| 2. Information about the drug that will be tested in the study | |
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| **Name of drug** | PQ912 (also named varoglutamstat) |
| **Administration** | Tablet |
| **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 tablet of PQ-912 once daily (evening)<br>• An oral tablet of placebo (inactive substance identical in appearance to the drug being tested).<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 safety, tolerability and efficacy of PQ912 in people with mild cognitive impairment and mild dementia due to Alzheimer's disease. |
| **How long will the treatment last?** | • The duration of participation in the study is either 48, 60, 72, 84 or 96 weeks of treatment. |
| **What your involvement will entail?** | • During the study, participants will have to undergo brain scan (MRI) to see if they have amyloid pathology in their brain<br>• Complete some laboratory tests and neurological |

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| | examinations to evaluate the emergent adverse effects (unfavourable signs, symptoms or diseases temporally associated with the use of the drug tested in the study)<br><br>• During the study, participants will be asked to complete other tests that will assess their memory, functioning, attention and psychomotor function (i.e. tests or scales like CBB-Z, NTB)<br><br>• Do physical examination and an electroencephalography (a test that records the electrical activity of the brain).<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 80 years old<br><br>• Have a diagnosis of mild cognitive impairment or mild Alzheimer's disease according to the National Institute on Aging/Alzheimer's Association core clinical criteria<br><br>• Have adequate visual and auditory abilities to perform the cognitive and functional assessments in the opinion of the investigator<br><br>• Have a study partner who has a sufficient contact with the participant, is willing to participate in study procedures throughout the study duration. |
| **Who cannot participate in the study?** | Exclusion criteria include:<br><br>• Any other type of neurological or psychiatric disease that is not Alzheimer's disease (e.g. epilepsy) that may affect cognition<br><br>• History of schizophrenia (mental disorder which affects how a person thinks, feels and acts) or other depressive |

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| | disorder<br>• History of a stroke, transient ischemic attack or seizures within the past two years<br>• Contraindication to MRI procedures and lumbar puncture.<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 (active)** | • Denmark<br>• Germany<br>• Netherlands |
| **Estimated start date of recruitment** | July 2020 |

| **6. Information for your doctor** | | | |
|---|---|---|---|
| **EudraCT Number**: | 2019-003532-23 | **Clinicaltrials. gov identifier** | NCT04498650 |
| **Study contact information** | Katharina Fuchs +49 5559900<br>Kerstin Kuehn-Wache +49 5559900<br>clinics@vivoryon.com | | |
| **Link to full text** | https://clinicaltrials.gov/ct2/show/NCT04498650 | | |

- ✓ The information contained in this document is based on information available on public registries (e.g. clinicaltrials.gov website) on January 2021.
- ✓ 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.