Alzheimer Europe

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

# CLINICAL TRIALS WATCH

## ACCESSIBLE EASY READ INFORMATION ON:

# ITI-1284-201 STUDY

**Alzheimer Europe** • R.C.S. LUXEMBOURG F2773 • 5 Heienhaff, L-1736 Senningerberg
Tel. +352 29 79 70 • Fax +352 29 79 72 • info@alzheimer-europe.org • www.alzheimer-europe.org

# ITI-1284-201 study

| 1. Study Information | |
|---|---|
| **Name of the study** | A study to assess the efficacy and safety of ITI-1284 in the treatment of psychosis associated with Alzheimer's disease |
| **Study sponsor** | Intra-Cellular Therapies Inc. |
| **Disease** | Psychosis associated with Alzheimer's disease |
| **Phase** | Phase II |

| 2. Information about the drug that will be tested in the study | |
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| **Name of drug** | ITI-1284 |
| **Administration** | Oral tablet once daily (sublingual administration) |
| **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 ITI-1284 (10mg)<br>• An oral tablet of ITI-1284 (20mg)<br>• An oral tablet of placebo (also called a dummy treatment which is an inactive substance identical in appearance to the drug being tested with no active therapeutic effect).<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 | |
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| **What are the researchers trying to find out?** | • The study will evaluate the efficacy, safety, and tolerability of ITI-1284 compared with placebo in the treatment of psychosis in patients with Alzheimer's disease. |
| **How long will the treatment last?** | • The treatment period is 6 weeks |

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| | • The treatment period will be followed by a safety follow-up period of 30 days which all participants will return for a safety follow-up visit approximately 30 days after the last dose of study drug. |
| **What your involvement will entail?** | • During the study, participants will be asked to complete tests that will assess their psychotic symptoms (BEHAVE-AD test) and overall mental health (CGI-S test).<br><br>Further information on the procedures, tests and 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 55 years old and older<br><br>• Be able to provide consent before the initiation of any study-specific procedures<br><br>• Have a body mass index (BMI) of 18–40 kg/m2 inclusive<br><br>• Have a diagnosis of Alzheimer's disease according to the 2011 NIA-AA criteria<br><br>• Have evidence of abnormal accumulation of amyloid in the brain (determined either through CSF examination (lumbar puncture) or with the use of an amyloid PET scan or confirmed by blood-based biomarker)<br><br>• Have psychosis in accordance with the International Psychogeriatric Association (IPA) provisional consensus definition and must have score above 2 on any item of the BEHAVE-AD test<br><br>• Have a score between 6 and 24 points in the MMSE test (a test about your general thinking skills) |

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| | • Have a study partner who has a sufficient contact with the participant, is willing to participate in study procedures throughout the study duration. |
| **Who can't participate in the study?** | Exclusion criteria include:<br><br>• Psychotic symptoms that are primarily attributable to delirium, substance abuse, or another general-medical condition (e.g., hypothyroidism) or diagnosis of psychiatric conditions such as schizophrenia and bipolar disorder<br><br>• Risk for suicidal behavior<br><br>• Hospitalisation or receiving skilled nursing care for any medical condition other than dementia<br><br>• Hospice or end-of-life care.<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?** | |
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| **European countries involved in the trial (active)** | • Bulgaria<br>• Croatia<br>• Czechia<br>• Poland<br>• Romania<br>• Slovakia<br>• Spain |
| **Estimated start date of recruitment** | July 2025 |

| 6. Information for your doctor | | | |
|---|---|---|---|
| **Clinicaltrials.gov identifier** | NCT06540833 | **EUCT number** | 2024-513035-25-00 |
| **Study contact information** | ITCIClinicalTrials@itci-inc.com | | |
| **Link to full text** | https://clinicaltrials.gov/study/NCT06540833<br>https://euclinicaltrials.eu/ctis-public/view/2024-513035-25-00 | | |

- ✓ The information contained in this document is based on information available on public registries (e.g. CTIS, clinicaltrials.gov websites) in November 2025.

- ✓ This document has been reviewed by a member of the European Dementia Carers Working Group.