ALZHEIMER'S DISEASE CLINICAL STUDY
INCLUSION-EXCLUSION CRITERIA

Inclusion

- Men or women, patients aged between 55 and 90 years, inclusive, at the time of the evaluation (visit 1).
- Patients diagnosed with possible AD (Alzheimer's Disease) or probable AD.
- The patient must have a magnetic resonance imaging (MRI) or a computed tomography (CT) scan of the brain (performed within the last 5 years) taken during or after the onset of dementia to rule out other central nervous system (CNS) diseases that could explain the dementia syndrome, such as major stroke, neoplasm, or subdural hematoma.
- Living in the same household or assisted living facility for at least 6 weeks prior to the start of the study.
- Ability to move and have a study partner who assists the participant and supervises their adherence to the protocol.
- The patient must have a history of psychotic symptoms (meeting the criteria of the International Psychogeriatric Association) for at least 2 months prior to the evaluation (visit 1) (participants may or may not have symptoms of agitation).
- If taking cholinesterase inhibitors or memantine, they must be on a stable dose for 6 weeks prior to the start of the study.

Exclusion

Medical Conditions:
- Psychotic symptoms not related to Alzheimer's disease (AD), such as schizophrenia or mood disorders with psychotic features.
- Serious illnesses such as pulmonary, hepatic, renal, cardiovascular diseases, cancer, among others, that could compromise the participant's safety or affect the validity of the study.
- History of strokes (ischemic or hemorrhagic) or serious neurological conditions such as epilepsy.
- Severe cardiac conditions such as congestive heart failure or significant angina, and a history of severe arrhythmias (ventricular tachycardia, ventricular fibrillation).
- Severe gastrointestinal or urinary disorders, such as irritable bowel syndrome or urinary retention.
- Risk of suicidal behavior based on the clinical assessment of the investigator.

Reproductive Status:
Women who are breastfeeding cannot participate in the study.

Previous or Concurrent Treatments:
- Previous exposure to KarXT.
- Concurrent treatments that are incompatible with the study, such as potent anticholinergic medications.
- Recent use of monoamine oxidase inhibitors, anticonvulsants, or psychoactive medications within the 6 weeks prior to screening.

Physical and Laboratory Test Results:
- Significant clinical abnormalities in the physical examination, ECG, or laboratory results during screening.
- Positive urinary toxicology test for prohibited substances (except cannabis or benzodiazepines).
- Severe renal insufficiency.

Allergies and Adverse Drug Reactions:
History of severe adverse reactions to trospium or known hypersensitivity to it.

Other Exclusion Criteria:
Prisoners or individuals involuntarily incarcerated (except under specific circumstances). Recent participation in another clinical trial or receipt of an experimental drug within the last 3 months. If the investigator believes that the participant is not suitable for the study or that their inclusion may compromise safety or protocol compliance.

BENEFITS OF PARTICIPATING IN THE STUDY:

- Monetary compensation for your time.
- Access to a doctor and medical studies.
- Access to new medications for treating Alzheimer's.
- Round-trip transportation to Nexus.

If you are interested in referring a participant or if you have any questions, you can contact us directly:

(305)- 767-0708

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