

NEUROSENTIA™ – Clinical Evaluation

Title

A Multi-Center, Double-Blind, Placebo-Controlled Study Evaluating the Safety and Efficacy of NEUROSENTIA™ in Adults With Moderate to Severe Alzheimer's Disease

Product Name

NEUROSENTIA™ – Advanced Memory Defense

Formulation Type

Oral Capsule

Trial Phase

Phase II (Planned)

Trial Start

Fall 2025

Background and Rationale

Alzheimer's disease (AD) is a progressive neurodegenerative disorder marked by memory loss, cognitive dysfunction, and neuronal degeneration. Despite decades of research, few interventions demonstrate meaningful efficacy, especially in moderate to severe stages.

NEUROSENTIA™ is a proprietary, multi-ingredient nutraceutical formula developed to restore cognitive performance, enhance neuroplasticity, and slow neurodegeneration using a synergistic approach.

NEUROSENTIA™ targets multiple biological pathways involved in Alzheimer's pathology including:

- Amyloid-beta aggregation
- Tau hyperphosphorylation
- Cholinergic dysfunction
- Neuroinflammation
- Oxidative mitochondrial stress
- Blood-brain barrier permeability

Clinical Objectives

Primary Endpoint:

- Change from baseline in the Alzheimer's Disease Assessment Scale-Cognitive Subscale (ADAS-Cog13) at 24 weeks

Secondary Endpoints:

- Improvement in MMSE (Mini-Mental State Exam) scores
- Changes in Neuropsychiatric Inventory (NPI) scores
- Caregiver burden assessment via Zarit Burden Interview
- Brain imaging changes (optional): hippocampal volume, cortical thickness (MRI subset)
- Biomarkers: serum BDNF, homocysteine, and inflammatory cytokines

Study Design

Design: Randomized, placebo-controlled, double-blind, multi-center

Duration: 6-month active treatment + 3-month follow-up

Population: 300 participants across 10 sites (U.S., Europe, Latin America)

Inclusion Criteria: Age $\geq$ 60, MMSE score 10–20, clinical diagnosis of moderate-to-severe AD

Exclusion Criteria: Renal or hepatic failure, recent major stroke, antipsychotic use

Safety Profile

All ingredients in NEUROSENTIA™ are classified as Generally Recognized as Safe (GRAS) or approved for dietary supplement use.

Prior internal pilot testing in 26 participants showed no major adverse events.

Liver, kidney, and cardiovascular monitoring will be implemented in clinical evaluation.

Regulatory Pathway

NEUROSENTIA™ will be evaluated as a dietary supplement undergoing clinical validation, not as a pharmaceutical, aligning with FDA DSHEA compliance. The study protocol will be submitted to IRBs at each participating institution and entered into ClinicalTrials.gov.

Trial Sites (Planned)

- Johns Hopkins Memory & Aging Center (USA)
- Cleveland Clinic Neurology (USA)
- Karolinska Institute (Sweden)
- University of São Paulo (Brazil)
- Max Planck Institute for Brain Research (Germany)

Conclusion

NEUROSENTIA™ is a scientifically grounded, multi-target neuroprotective supplement poised for clinical evaluation in the fight against Alzheimer's disease. Its holistic, evidence-based approach aims to bridge the gap between traditional pharmaceuticals and real-world, multi-pathway brain support.