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Sponsor

Stemedica Cell Technologies,
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CLINICAL TRIAL ANNOUNCEMENT

Phase IIA Trial to Evaluate **Allogenic Stem Cells** in Patients with Mild to Moderate **Dementia** due to Patients with **Alzheimer's Disease**

Official Title:

A Phase IIA, Multi-Center, Randomized, Single-Blind, Placebo-Controlled, Crossover Study to Assess the Safety, Tolerability, and Preliminary Efficacy of a Single Intravenous Dose of Allogenic Human Mesenchymal Stem Cells to Subjects with Mild to Moderate Dementia due to Alzheimer's Disease

The purpose of this study is to assess the safety and tolerability of ischemia-tolerant allogeneic human mesenchymal stem cells (hMSCs) administered intravenously in all patients enrolled.

Alzheimer's disease is the most common cause of dementia among older adults. It is currently ranked as the sixth leading cause of death in the United States. Pre-clinical experiments conducted by Stemedica using intravenous (IV) delivery of hMSCs demonstrated efficient Abeta amyloid plaque removal in the brain parenchyma of the APPPS1 mouse model. The beneficial effect on Abeta plaques was accompanied by an overall decrease in neuroinflammation markers without the appearance of amyloid clearance side effects.

Two cohorts, Cohort 1 (IV dose of hMSCs at 1.5 million cells/kg body weight on Study Day 1) and Cohort 2 (equal volume of Lactated Ringer's Solution on Study Day 1). At 6-month timepoint, Cohort 1 will receive a second IV dose of hMSCs at 1.5 million cells/kg body weight and Cohort 2 will receive a single IV dose of hMSCs at 1.5 million cells/kg body weight.

Key Inclusion Criteria:

- Age 55-80 years
- Diagnosed with mild to moderate dementia for at least 3 months
- MMSE between 12-24 (inclusive) at time of enrollment
- Amyloid-positive florbetapir PET scan

Key Exclusion Criteria:

- Prior treatment with stem cells
- History of intracranial, subdural, or subarachnoid hemorrhage
- Subjects with baseline brain MRI showing more than four (4) cerebral micro-hemorrhages
- History of seizure disorder
- History of cerebral neoplasm