INCLUSION/EXCLUSION CRITERIA

DIAGNOSIS OF AD	Diagnosis of AD will be confirmed in ALL patients by: • Medical History • Physical Exam • Diagnostic tests - routine blood work to rule out hypothyroidism, B12 deficiencies, etc. • Neurologic Exam (independent neurologist) • Mental status exam – MMSE and MoCA and ADL scores • Biomarkers per NIA-AA 2018 Criteria* (from CSF AdMark P-Tau, total Tau and Aß1-40 testing, Athena Labs) • Brain imaging: AD diagnosis including CSF Amyloid &/or Positive Amyloid by FDG PET scan at baseline screening • Neuroquant volumetric MRI References: 10.1016/j.jalz.2018.02.018, 10.1016/j.jalz.2016.02.002

INCLUSION CRITERIA FOR PARTICIPANTS	1. Written informed consent. 2. Participant age range: adult participants, 45 to 80 years of age, inclusive. 3. FAST stages 4 and 5.* 4. MMSE 11-20 and/or MoCA score 11-20. 5. CSF ADmark within the AD histogram region c/w AD. 6. MCI Screen 7. ADAS-cog score >16. 8. Participant must be able to provide informed consent*. 9. The caregiver must separately meet the specified inclusion/exclusion criteria for caregivers. 10. Women of child-bearing potential who agree to use suitable methods of contraception. 11. MRI Quant: structural evidence for AD diagnosis including hippocampal volume loss &/or total brain volume loss greater than 1.5 standard deviations from the norm. 12. MRI brain with contrast showing no tumor or other disease responsible for dementia. 13. Amyloid PET with greater than 1.5 standard deviations from the norm.

	14. Supportive evidence for AD diagnosis including CSF Amyloid &/or Positive Amyloid by FDG PET scan at baseline screening. 15. Health: physically healthy and ambulatory or ambulatory-aided (i.e., walker or cane); corrected vision and hearing sufficient for compliance with testing procedures, and able to read prior to disease onset. 16. Clinical laboratory values must be within normal limits or, if abnormal, must be judged not clinically significant by the investigator. 17. Specified doses of selective serotonin reuptake inhibitors (SSRI's) are allowed in the study if dosage is within approved dose range and stable for 3 months prior to Screening. 18. Other medical conditions, such as hypertension and cardiac disease must be well-controlled, and the participant maintained on stable doses of medications for 3 months. 19. Participants with diabetes mellitus or risk factors for diabetes mellitus may be enrolled in the study provided that the participants disease is stable and that there have been no recent hospitalizations for diabetes complications. 20. Participants whose serum B12 levels at Screening are below the normal range may nonetheless be admitted to the study if they subsequently show normal levels prior to Baseline. 21. Participants with hypothyroidism who are on a stable dose of medication for at least 12 weeks prior to Screening, have normal TSH and free T4 at Screening, and are considered euthyroid will be eligible. 22. Concomitant Medications: Underspecified circumstances, the following medications may be allowed: chronic daily benzodiazepine use, bronchodilator medications for treatment of chronic obstructive pulmonary disease (COPD) and memantine. Current AD medications such as donepezil or AChE's including patches are allowed as long as participants are on a stable acceptable dose. 23. The participant must have a relative/caregiver who supervises the regular taking of the drug at the correct dose and is alert for possible side effects, unless the participant's legal guardian takes on this task.

INCLUSION CRITERIA FOR CAREGIVERS	1 The designated caregiver must be sufficiently familiar with the participant (as determined by the investigator) to provide accurate data. 2 The caregiver must have regular contact with the participant (i.e., an average of 10 or more hours per week), must be able to observe for possible adverse events, and must be able to accompany the participant to all visits.

Exclusion Criteria for Participants:	1. Participants are excluded if they are taking other medications for Alzheimer's disease, except that donepezil memantine, AChE's including patches, Vitamin E, fish oil, and/or gingko biloba are allowed and their doses have been stable for at least 3 months prior to the Screening visit Participants undergoing any alternative medical techniques, such as acupuncture or acupressure, specifically for the treatment of AD are not eligible. 2. No form of stem cell implantation of any type within 3 months. 3. No caregiver available to meet the inclusion criteria for caregivers. 4. Participants with existing ventriculoperitoneal shunts. 5. Participants with neurological disorders that affect cognition or the ability to assess cognition but are distinguishable from Alzheimer's disease. These include but are not limited to, Parkinson's disease, multi-infarct dementia, and dementia due to cerebrovascular disease, Lewy body disease_ 6. Participants with psychiatric disorders affecting the ability to assess cognition such as schizophrenia, bipolar or unipolar depression. Participants with clinically significant sleep disorders will also be excluded unless these are controlled by treatment and clinically stable for > 3 months prior to screening. 7. Participants with dementia complicated by other organic disease or Alzheimer's disease with delirium. 8. Participants with drug or alcohol abuse or dependence ·within the past 5 years according to DSM Criteria.

	9. Participants with evidence of clinically significant, active gastrointestinal, renal, hepatic, respiratory, endocrine, or cardiovascular system disease (including history of life-threatening arrhythmias). 10. Participants with a history of cancer (does not include basal or squamous cell carcinoma of the skin) treated within 5 years prior to study entry, or current evidence of malignant neoplasm, recurrent, metastatic disease. Males with localized prostate cancer requiring no treatment would not be excluded. 11. Known plan for elective surgery during the treatment period that would require general anesthesia and administration of neuromuscular blocking agents. 12. Donation of blood or blood products during 30 days prior to Screening or plans to donate blood while participating in the study or within 30 days after completion of the study. 13. Participants who are unwilling or unable to fulfill the requirements of the study. 14. Use of any prohibited prior or concomitant medications) Any condition that would make the participant, in the opinion of the investigator, unsuitable for the study. 15. Involvement in any other investigational drug clinical trial during the preceding 3 months, or likely involvement in any other such trial during the course of this study. 16. Participants taking concomitant antidepressant medication known to have significant anticholinergic effects, such as tricyclic antidepressants prescribed at doses recommended for the treatment of major depression. 17. Participants with fecal and/or urinary incontinence who are unable to cooperate with routine specimen collection.
Exclusion Criteria for Caregivers:	1. Caregivers who are unwilling or unable to give informed consent or otherwise unable to fulfill the requirements of the study. 2. Any condition that would make the caregiver, in the opinion of the Investigator, unsuitable for the study.