Clinical Evaluation of T3D-959 as a Potential Disease Remedial Therapeutic for the Treatment of Alzheimers Disease

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Contact information of lead PI
Country

USA

Title of project or programme

Clinical Evaluation of T3D-959 as a Potential Disease Remedial Therapeutic for the Treatment of Alzheimers Disease

Source of funding information

NIH (NIA)

Total sum awarded (Euro)

€ 1,756,783.49

Start date of award

15/03/2015

Total duration of award in years

2

The project/programme is most relevant to:

Alzheimer's disease & other dementias

Keywords

Acquired Cognitive Impairment... Aging... Alzheimer's Disease... Alzheimer's Disease including Alzheimer's Disease Related Dementias (AD/ADRD)... Brain Disorders... Clinical Research...

Clinical Research - Extramural... Clinical Trials and Supportive Activities... Dementia... Diagnostic Radiology... Effectiveness Research... Endocrine System... Neurodegenerative... Neurosciences... Translational Research

Research Abstract

DESCRIPTION (provided by applicant): The purpose of the proposed project is to conduct a Phase 2a mechanistic clinical proof of concept study of an investigational drug, T3D-959 which is being developed for the treatment of cognitive and functional decline in Alzheimer's disease patients. T3D-959 has successfully completed Phase I studies, and with data demonstrating robust entry into the brain in a rat pharmacokinetic study. T3D-959 is a novel, orally delivered, small molecule, dual nuclear receptor agonist, formerly targeted as a type 2 diabetes therapy and now being re-positioned as a potential disease-modifying therapy for Alzheimer's disease (AD) and mild cognitive impairment (MCI). The project goal is to test the hypothesis that T3D-959 can mechanistically act in the brain of AD patients to produce desired changes in glucose metabolism (as measured by FDG-PET) and brain function (as measured by BOLD fMRI). These imaging modalities are currently being utilized as surrogate measures of potential efficacy in treating AD. If T3D- 959 treatment produces desired changes in glucose metabolism and brain function, the drug could have disease remedial potential and this study could provide supportive clinical data that justifies the pursuit of longer term clinical studies of the potentia of T3D-959 to slow, stop or reverse cognitive and functional decline in AD patients. The clinical trial is an adaptive, sequential enrollment design involving 24-36 mild-to-moderate AD patients dosed orally once-a-day for 2 weeks. The project has 3 key objectives: i. To determine the potential of T3D-959 to improve cerebral glucose metabolism (CMRgl). Low CMRgl is a hallmark of AD and a better predictor of future cognitive impairment than amyloid plaqe or tau bundle load. ii. To determine the potential of T3D-959 to improve memory-related hippocampal functional connectivity (resting state default mode network activity). iii. Determine appropriate doses for future clinical studies (dose range finding). The therapeutic approach to be tested is based on two suppositions; (A) ameliorating multiple pathologies in the disease with a single therapy may provide a superior clinical benefit than therapeutic approaches which target a single pathology (e.g. beta amyloid plaques) and (B) correcting insulin resistance in the brain, (a key driver of AD pathophysiology) may be disease remedial.

Lay Summary

PUBLIC HEALTH RELEVANCE: Alzheimer's disease today is the costliest disease to the American healthcare system with no marketed drug therapies that can slow, stop or reverse the course of this malady. The purpose of the proposed project is to conduct a mechanistic proof of concept Phase 2a study of an investigational drug, T3D-959, which has successfully completed Phase I. The project aims to demonstrate that T3D-959 has the potential to be an effective disease remedial drug therapy for treating cognitive impairment in Alzheimer's disease. The therapeutic approach to be tested is based on two suppositions; (A) ameliorating multiple defects in the disease with a single therapy may provide a superior clinical benefit than therapeutic approaches which target a single defect (e.g. beta amyloid plaques) and (B) correcting insulin resistance in the brain, (a key driver of Alzheimer's disease pathophysiology) may alter the course of disease.

Further information available at:

Types:

Investments > €500k

Member States:
United States of America

Diseases:
Alzheimer's disease & other dementias

Years:
2016

Database Categories:
N/A

Database Tags:
N/A