U.S. Food and Drug Association Approves Human Testing for Investigational New Drug for Alzheimer’s Disease

Vanderbilt University scientists have received notification from the U.S. Food and Drug Administration (FDA) that testing in humans may proceed for an investigational new drug after more than 10 years of research.

The aim is for the investigational drug to target major pathologies of Alzheimer’s disease and selectively activate a key receptor in the brain. The researchers believe that the current standard of care for Alzheimer’s disease (i.e., cholinesterase inhibitors) has a different mechanism of action. They are hoping to establish, through future clinical testing, that the molecule is broadly effective across a number of cognitive and neuropsychiatric disorders, including schizophrenia.

Phase 1 testing will assess drug safety and tolerability in healthy volunteer participants—a process that could take 1 year. If successful, Phase 2 and 3 studies would include efficacy assessments in patients with Alzheimer’s disease and could take 3 to 5 years to complete.


Eli Lilly and AstraZeneca to Co-Develop MEDI1814 as Disease-Modifying Treatment for Alzheimer’s Disease

Eli Lilly and AstraZeneca announced a worldwide agreement to co-develop MEDI1814, an antibody selective for amyloid-beta 42 (Aβ42), which is currently in Phase 1 trials as a potential disease-modifying treatment for Alzheimer’s disease.

The buildup of plaques in the brain containing the peptide amyloid-beta (Aβ) is one of the characteristics of Alzheimer’s disease. MEDI1814 binds selectively to Aβ42, a form of Aβ that is particularly associated with the disease. Binding dose-dependently reduces levels of this peptide, potentially slowing the progression of Alzheimer’s disease.