Cognoptix

Pioneering the Early Detection of Alzheimer's Disease

Alzheimer's disease is the sixth leading cause of death in the U.S and is the only chronic disease with an increasing incidence rate without a definitive and actionable diagnostic. The diagnostic process is very challenging often multi-year process for physicians, occurs late in the disease and it is often inaccurate (up to 30% misdiagnosed). This results in worse patient outcomes and adds to the high costs associated with caring for Alzheimer's patients. This high unmet medical need is even more pressing as we are at the cusp of new class of disease modifying therapies that are amyloid targeting and require an easy but reliable screening tool for detecting amyloid-positive patients eligible for these new therapies. It is now widely accepted that these new therapies will have the most impact the earlier the patients receive them.


Susanne Wilke

The most promising basis for a more definitive diagnosis is the detection of the protein biomarker, beta amyloid, which aggregates in the early stages of the disease. Based on the 2018 research criteria established by the National Institute of Aging in collaboration with the Alzheimer's Association (NIA – AA criteria), it is the presence of amyloid as the earliest detectable dysregulated AD biomarker that defines the disease. Unfortunately, the only FDA approved technology for detecting beta amyloid, is the PET amyloid, which is very costly, not widely available and exposes the patient to a significant amount of radiation and only detects AD late in the disease progression. Therefore it is not surprising that less than 3% of the estimated current 5 million people with AD in the US have received a PET scan. Cognoptix's Sapphire II System is poised to fulfill this large unmet medical need.

Cognoptix is a leading medical diagnostics company for Alzheimer's developing a simple and innovative non-invasive eye scanning test to address this need. The company's proprietary diagnostic system, Sapphire II, includes a laser eye scanning device and a fluorescent ligand containing ophthalmic ointment that binds to beta amyloid with high specificity. The automated ophthalmic laser scanner scans the eye and provides a quantitative measure of the amyloid present in the lens and generates accurate results in less than five minutes. "We have several scientific and longitudinal clinical studies showing that we can detect amyloid in the early stages of AD in the patients' eyes. This diagnostic test is a critical enabler of early therapeutic intervention when patients can most benefit from treatment and non-pharmacological interventions.", states Dr.Susanne Wilke, the President and CEO of Cognoptix.

One of the most exciting aspects of the Sapphire technology is the possibility that detecting amyloid in the lens may have advantages over detecting amyloid the brain. The lens of the eye, embryonically derived from the same stem cells as neurons produces amyloid in the lens of the ocular lens by the same mechanism as the brain but it accumulates in the lens earlier due to a lack of the metabolic degradation and removal processes that initially helps clear the amyloid from the brain. This may make the Sapphire II diagnostic test ideally suited for early stage detection of amyloid pathology. This early stage detection is critical if physicians and patients are to fully realize the benefits of the next generation of disease modifying therapies (DMT) coming to market. There are a number of DMTs in development and the furthest along, Biogen's Aducanumab, has been submitted to and could be approved by the FDA as early as April 2021. Another important therapy on the horizon is Eisai's BAN2401 which is being studied in even earlier stage patients, some of which may have only the mildest clinical symptoms.

Unlike the FDA approved amyloid PET scan that uses radioactive ligand to test for AD and costs anywhere between $5-8K, Cognoptix's Sapphire II is designed to be easily accessible to everyone and cost only $300 to $800/scan. "Sapphire II is an accessible, easy to administer, and safe test to detect and diagnose Alzheimer's and importantly, helps differentiate AD from other causes of cognitive decline in patients" concludes Dr. Wilke.

Cognoptix is about to enter the final stage of its development program and will conduct a pivotal study that aims to replicate the strong results seen in its pre-pivotal program. Data from the pre-pivotal study in the MCI population suggest that Sapphire II may be more sensitive in detecting early disease than PET. This exciting possibility will be tested in subsequent studies as the company continues to explore the potential for its breakthrough technology.