# Cognoptix begins pre-pivotal clinical trial of its drug/device test designed to identify Alzheimer's disease via beta amyloid signature in the eyes

The Associated Press

ACTON, Mass.--(BUSINESS WIRE)--Feb 28, 2013--Cognoptix announced today that it has begun a 40-patient clinical trial of its SAPPHIRE II eye test designed to identify Alzheimer's disease patients via a beta amyloid ("Ab") signature in their eyes. By detecting a specific fluorescent signature of ligand-marked beta-amyloid in the supranucleus region of the human lens, SAPPHIRE II achieved a two-fold differentiation factor between a group of five healthy volunteers and a group of five patients diagnosed with probable Alzheimer's disease in a recent proof-of-concept clinical trial.

Cognoptix has exclusively licensed groundbreaking technology from the University of California at San Diego ("UC San Diego"), which Cognoptix has developed into an innovative, non-invasive eye-scanning test, SAPPHIRE II, for the early detection and diagnosis of Alzheimer's disease ("AD") pathology. The UC San Diego technology is the subject of a scientific paper recently published in the peer-reviewed Journal of the American Chemical Society ("Aminonaphthalene 2-Cyanoacrylate [ANCA] Probes Fluorescently Discriminate between Amyloid-β and Prion Plaques in Brain"). In addition to UC San Diego, exclusive licenses have been acquired from Massachusetts General Hospital and Brigham and Women's Hospital Boston.

"There is considerable scientific scrutiny looking at the function of beta amyloid neuritic plaques in the brains of adult patients who have cognitive impairment and possible Alzheimer's disease," said Carl Sadowsky, M.D., Medical Director at Premiere Research Institute in West Palm Beach, Fla., and a principal investigator in the SAPPHIRE proof-of-concept and the current clinical study. "While PET (Positron Emission Tomography) imaging is approved to facilitate identification of beta amyloid neuritic plaques in living AD patients, there is still a dire need for an inexpensive, non-invasive technology for perfecting the differential diagnosis of dementia that could be applicable for broad use at the point-of-care." "We are pleased to be participating in this important study, because there is a critical need for a fast, prophetic, dependable, low-cost and readily available test for the early diagnosis and management of Alzheimer's disease," added Pierre N. Tariot, M.D., Director of the Banner Alzheimer's Institute in Phoenix, and a principal investigator on the Cognoptix trial.

"There is no early-stage, non-invasive diagnostic test for Alzheimer's disease in the market," added Paul Hartung, President and CEO of Cognoptix. "This is very unfortunate because patients often incur up to one-half of neuronal loss and a delay of up to 24 months before exhibiting severe enough symptoms to be diagnosed by the current gold standard: a 'process of elimination' of other potential diagnoses including stroke, trauma, Parkinson's disease and dementia, by means of extensive

cognitive and physical testing. On the other hand, there are nearly 100 new therapeutic drugs to slow or stop the progress of AD that are expected to reach the market soon. Cognoptix is developing a simple system of early-stage diagnosis to allow treatment before significant neuronal loss and irreversible brain damage happens." About SAPPHIRE II Cognoptix has developed an in-office, drug/device diagnostic system designed as an aid in the early detection of Alzheimer's Disease (AD) pathology. A ligand or contrast agent (drug) and software-controlled optical instrument (device) allows for noninvasive detection and assessment of AD by measuring the hallmark of AD, beta amyloid, in the supranuclear region of the lens of the eye. The ligand is easily administered to the eye as an ophthalmic ointment and a proprietary Fluorescent Ligand Scanning (FLS) instrument, provides an objective and quantitative measurement of beta amyloid in the patient's lens. Significantly faster and an order of magnitude less expensive than brain-imaging, the test and diagnosis are designed to be quickly completed in any physician's office, including general practitioners.

About Cognoptix
Cognoptix, a privately held medical technology company headquartered in Acton, Mass., is focused on developing and commercializing an in-office, drug/device diagnostic system as an aid in the early detection of Alzheimer's Disease (AD). Its investors include Inventages Venture Capital, one of the world's largest life sciences-, nutrition- and wellness-focused venture capital firms; and Launchpad Venture Group, a Boston-based angel investment firm that provides funding to early-stage companies.