

News Release

Researchers study potential new therapeutic target for Alzheimer's disease

Medical centers in Kalamazoo and Grand Rapids referring individuals for participation in a clinical trial

KALAMAZOO, Mich., June 21, 2012 – Physicians at medical centers in Kalamazoo and Grand Rapids are helping to identify interested individuals for participation in a clinical trial of a novel drug therapy for patients with dementia due to Alzheimer's disease. MSDC-0160, a new drug which is also being developed as a treatment for diabetes by Kalamazoo-based Metabolic Solutions Development Company, LLC (MSDC), modulates mitochondrial metabolism which may play an important role in brain cell survival.

According to the Alzheimer's Association, researchers are exploring how brain cells use glucose and produce energy. These investigations may reveal strategies to support cell function and stave off Alzheimer-related changes.²

"In this initial study, we are trying to determine if MSDC-0160 improves the brain's use of glucose," said Dr. Raj C. Shah, director of the Rush Memory Clinic at the Rush Alzheimer's Disease Center and principal investigator of the study. "We can measure brain cell glucose utilization by using a special brain imaging technique called fluorodeoxyglucose positron-emission tomography, or FDG-PET."

Dr. William H. Baer from VARI-ClinXus, the translational research arm of Van Andel Institute (Grand Rapids) and Dr. Phillip M. Green from the Borgess Research Institute (Kalamazoo) are providing information about the study to residents of West Michigan interested in taking part.

According to Dr. Baer, "With Alzheimer's disease it is most often the community physicians on the front lines who are the first to evaluate patients with dementia. Treatments, however, are limited. To give patients the most effective chance to modify or slow the progression of Alzheimer's, we need to connect patients to the latest clinical trials and research options as soon as possible."

"Early detection of Alzheimer's can be challenging and once a diagnosis is made, there is still no cure. It is imperative we provide increased access to clinical trials that can potentially modify the onset of the disease for our patients and ultimately, lead to a breakthrough in care," said Phillip M. Green, MD, Borgess Research Institute.

Patients who are 55-85 years of age, who do not have diabetes, and who have been diagnosed with mild dementia due to Alzheimer's disease are being enrolled in the clinical trial. Patients in the study will be randomized to receive either MSDC-0160 or a placebo once daily for 90 days. Patients will also undergo two FDG-PET brain imaging scans.

About Alzheimer's Disease

More than 180,000 people living in Michigan age 65 years old and older suffer from Alzheimer's disease, an increase of 6% from the year 2000, and a figure that is expected to increase 25% to 190,000 in 2025. Nationally, an estimated 5.4 million people are living with the disease. Alzheimer's is the sixth-leading cause of death in the US and the only cause of death among the top 10 in the United States that cannot be prevented, cured or even slowed.¹

While FDA-approved drugs now available for Alzheimer's treat some symptoms of the disease by helping memory and thinking problems in some patients, the hope is that next generation drugs will help modify the disease process.

About MSDC-0160

MSDC-0160 is a novel insulin sensitizer that modulates mitochondrial metabolism. Growing evidence suggests that loss of mitochondrial function, resulting in a corresponding decline in brain glucose metabolism, could be a contributing cause of Alzheimer's disease. The current clinical study will help determine if MSDC-0160 affects glucose utilization in specific regions of the brain and whether conducting future large-scale clinical studies in patients with mild Alzheimer's disease is warranted.

An earlier preclinical study in a mouse model conducted by researchers at the University of Illinois at Chicago indicated that MSDC-0160 may reduce Alzheimer's-like pathology in mouse brains. As a result of this finding, investigators at Rush University Medical Center in Chicago are conducting a Phase IIa trial that will help determine if the drug therapy affects glucose utilization in specific regions of the brain.

This clinical study, as well as the preclinical study at the University of Illinois at Chicago, has been funded by a grant from the Alzheimer's Drug Discovery Foundation.

For more information about this clinical trial for Alzheimer's disease, contact Dr. William Baer or Beth Eckhardt of VARI-ClinXus at (616) 234-5459 or (616) 485-2652; or Borgess Research Institute at (269) 226-4803.

About Metabolic Solutions Development Company

Metabolic Solutions Development Company (www.msdrx.com) is a drug discovery and development company investigating novel molecular targets and developing new therapeutics to treat metabolic diseases associated with age-related mitochondrial dysfunction, especially insulin resistance and type 2 diabetes. The company was founded in 2006 by former

researchers of The Upjohn Company and has raised more than \$55 million to support development of its lead compounds MSDC-0160 and MSDC-0602.

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¹ Alzheimer's Association. 2012 Alzheimer's disease facts and figures. *Alzheimer's and Dementia: The Journal of the Alzheimer's Association*. March 2012; 8:131–168.

²Alzheimer's Association website.

http://www.alz.org/research/science/alzheimers_treatment_horizon.asp