Investigational Drug Continues to Look Promising to Fight Early Alzheimer's
Sunnybrook Pioneers Compelling New Research Practice
as it Provides First-Ever Two Year Results

Toronto, ON (May 21, 2008) – Sunnybrook, together with British and Canadian researchers, has co-led the second phase of a study that suggests the drug Flurizan, at a higher dose, has the potential to safely modify and slow down the progression of Alzheimer's disease (AD) in its early stages.

Flurizan is an investigational drug being studied in patients with mild-to-moderate stages of the disease. "This is one of the first drugs to show the potential to not just treat the symptoms of AD, but also to slow down the disease itself if it is in the mild stage," says Dr. Sandra Black, co-principal investigator of the study, Neuroscience Research Director at Sunnybrook Health Sciences Centre and the mastermind behind the idea to extend the 12 month trial to 24 months at the participating Canadian sites. "As a phase 2 clinical trial, these results are preliminary, but they give some hope for the development of a new treatment for AD. The mild patients who were treated consistently over the course of the study declined very little over a two- year period, which is significant for patients and their families. It means they were still able to do things for themselves such as handling basic finances, making decisions, and looking after self-care needs."

In addition to the research findings, the study methodology was leading edge in dementia trials as practice, as the two-year study was critically important for detecting ongoing benefits, as previous studies in AD usually lasted six-months or perhaps a year maximum. "This study uses annual rate of change, important if you are hoping for disease modification. It's a new approach to assessing drug efficacy. To determine that you have changed the disease biology you want to know if you have flattened the slope of decline compared to placebo," says Dr. Black. "We found it is best to give the drug in the earlier stages of the disease. The effects only began to show around the nine-month point as you would expect if it took a while to impact on the disease process. The trend continued out to two years with an increasing difference over time."

The study results were published ahead of print. The findings indicate that for those in the milder stages of the disease treated at the higher dose (800 mg twice daily) of the drug, there was a significantly slower decline rate in activities of daily living and global function, which includes judgment, hobbies, and community activities. It did not however benefit patients with moderate stages of the disease at all. "It may be that the burden of the disease is too heavy to have an impact at that stage," says Dr. Black. "The evidence indicates the drug's best target is the earlier stage of dementia when people are still fairly independent in self care abilities."

Over a one-year period in both Canada and the U.K., the study involved testing 207 patients with mild-to-moderate severity of Alzheimer's Disease. A patient with mild AD is fairly independent but experiences some difficulty with more demanding activities such as handling finances. Patients who decline to moderate AD require more assistance for basic self-care activities, such as bathing and brushing teeth.

86 Canadian participants continued on into the second year of the study. They were randomized into three groups: two received treatment for a two-year period (either 400 or 800 mg twice a day), and one group received placebo for the first year and then began treatment on the drug in the second year. All three groups were tested using cognitive and function of daily living tests and a global function scale, which looks at one's ability to function at home, hobbies, etc. The drug appeared to be well tolerated with no serious drug-related side effects.

Amyloid is a sticky toxic protein that gradually deposits between nerve cells in the brain in Alzheimer's disease, damaging and killing cells. It is important to stop this abnormal buildup. Flurizan has an anti-amyloid action, gradually reducing the buildup of the production of the toxic protein, and potentially slowing progression of the disease.

Based on the preliminary results from the Phase II study, two larger Phase III clinical trials have been undertaken for an 18-month period each, involving 2400 participants. One based in the U.S. involves 1600 participants and has recently been completed and is now being analyzed. The other trial is a global study currently underway involving 800 participants in Canada, the US and Europe that will be completed in October 2008. Initial findings of the U.S. trial are expected to be announced in July 2008 at the International Congress for Alzheimer's Disease in Chicago. The global study's findings will be reported in the spring of 2009.

"If proven in the phase 3 study, the drug would be the first to bring real hope to modifying disease course. If safe and tolerable, and so far that looks promising, it could be taken safely for many years," says Dr. Sandra Black. With further research, it may prove to be useful as a regular preventative medication that high-risk patients would take to delay the onset of AD, similar to medications that help to prevent heart disease or stroke.

Dr. Gordon Wilcock, a geriatrician in the U.K., is the co-principal investigator of the study. The Canadian sites were members of the Consortium of Canadian Centres for Clinical Cognitive Research (C5R). Flurizan is produced by Myriad Pharmaceuticals, who sponsored the trial.

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