New Drug Looks Promising to Fight Early Alzheimer's January 4, 2006

Toronto, ON - Sunnybrook Health Sciences Centre, together with British and Canadian researchers, have led a study that suggests a new drug 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, head of Neurology at Sunnybrook Health Sciences Centre and internationally renowned researcher in AD. "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 study results were presented recently by Dr. Black at Neuroscience 2005, the Society for Neurosciences' 35th annual meeting in Washington. The findings indicate a significant trend of lesser decline in activities of daily living and global function, which includes memory, judgment, and hobbies.

Over a one-year period in both Canada and the U.K., Flurizan was tested in 207 patients with mild-to-moderate severity of Alzheimer's disease, which means they were in the earlier stages of the disease as defined by the Mini-Mental State exam; a score of 15 to 26 out of possible 30. 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 prompting for some basic self-care activities, such as bathing and brushing teeth.

The patients were randomized into three groups: two received treatment (either 400 or 800 mg), and one received placebo. All three groups were tested using communication and memory tests such as naming pictures, remembering a list of items and performing tasks such as addressing and stamping a letter.

The study results found the optimum dose is the higher dose of 800 mg, and the target population is people in the mild stages rated as 20 to 26 (not so much the moderate stages). The drug appears to be well tolerated with no serious drug-related side effects. The authors also note that the one-year study was important for detecting significant changes, as most studies in AD have only been for a six-month period. "We found it is best to give the drug in the earlier stages of the disease," says Dr. Black. "The effects only began

to show around the nine-month point as it is a slow process."

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," says Dr. Black. Flurizan has an anti-amyloid action, gradually reducing the buildup of the production of the toxic protein, and potentially slowing progression of the disease.

At the completion of the phase 2 study, over 80 per cent of eligible patients enrolled in a one-year partly-blinded continuation treatment study at the Canadian sites to retrieve more information on the drug's safety and to further identify the best dosage. The study is currently in its last few months, with patients participating in the treatment trial for a total of 24 months.

Based on the trial's preliminary results, a larger phase 3 clinical trial is now currently underway in the U.S., with hopes for a second Canadian and European trial in the late spring of 2006. "If proven in the phase 3 study, it might bring real hope to modify disease course. Hopefully, 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 in high-risk patients.

Dr. Gordon Wilcock, a geriatrician in the U.K., is the co-principal investigator of the study. The trial was peer reviewed by the Consortium of Canadian Centres for Clinical Cognitive Research (C5R). Flurizan is produced by Myriad Pharmaceuticals, an American bio-technology company. Myriad chose 31 research institutions in Canada and the U.K. to lead the Phase 2 developmental trial, with the majority of sites in Canada.

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Please Note

There are no trials of Flurizan currently underway in Canada. They are however recruiting patients for a clinical trial in the U.S.; more information on that trial can be requested by calling 1.888.459.4888

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