

Parkinson Society Canada
June 23, 2011

Title of Trial

A study to investigate the efficacy, safety and tolerability of Cogane™ (PYM50028) in early stage Parkinson's disease.

What is Parkinson's disease?

Parkinson's is a disorder of the brain. Movement is controlled by dopamine, a chemical that carries signals between nerves in the brain. When cells that produce dopamine die or are damaged, Parkinson's symptoms appear. Parkinson's is a complex condition causing motor symptoms, such as shaking, muscle stiffness, slowness of movement and impaired balance. Non-motor symptoms such as constipation, sleep disturbance, fatigue, depression and cognitive changes also occur. (See Parkinson Society Canada's Information Sheet on *Progression of Parkinson's Disease* at www.parkinson.ca)

How is Parkinson's disease treated?

Current treatment neither cures Parkinson's nor stops it from advancing. Since Parkinson's is a progressive condition, symptoms will worsen over time and new ones may appear. Medications will need to be adjusted; perhaps taking them more frequently or at higher doses or a combination of drugs may be required to control symptoms. Some people with Parkinson's may benefit from brain surgery (often known as deep brain stimulation). (See Parkinson Society Canada's Information Sheet on *Parkinson's Medications: What you need to know!* at www.parkinson.ca)

Why is this trial important?

Movement is controlled by dopamine, a chemical that carries signals between nerves in the brain. When cells that produce dopamine die or are damaged, Parkinson's symptoms appear. Most medications used to treat Parkinson's are aimed at replenishing or imitating dopamine; but often cause further complications and disability for the person (e.g., involuntary movements {dyskinesias} and non-motor symptoms, previously mentioned). The development of a therapy that may slow or stop the disease from getting worse would represent an advance in the treatment of Parkinson's.

What is being investigated?

This is a clinical trial to see whether a new compound Cogane™ may be beneficial in treating early Parkinson's. The new compound is a modulator of *neurotrophic factors*. *Neurotrophic factors* are proteins produced in the brain that help the survival, development and function of nerve cells. These proteins are produced naturally by the body to protect nerve cells. The compound is thought to work by stimulating the brain's production of these proteins. The research will study whether the compound could slow or reverse the progression of the disease caused by nerve damage.

What kind of study is this?

This is a Phase II, randomized, double-blind, placebo-controlled study testing the effectiveness, safety and tolerability of the new compound. Participants will be randomly assigned to one of four groups: three groups will receive the active compound at a low, mid or high dose; the fourth group will receive a placebo. Neither the participants nor the researchers will know who will be taking the active compound. (For more information on clinical trials, visit http://www.parkinson.ca/site/c.kgLNiWODKpF/b.3536159/k.9C4D/Clinical_Trials.htm).

Who can participate?

The study is seeking men and women between the age of 35 and 75 years who have been diagnosed with Parkinson's within the last 2 years. Participants should not be taking any medication to manage their Parkinson's symptoms. They should be in good general health and willing to meet the scheduled visits in the study.

People will not be able to participate if their Parkinson's symptoms include postural instability. Participants cannot participate if they have any of the following:

- --severe cognitive impairment
- --current or past history of major depression and/or psychiatric illness
- --a diagnosis of atypical Parkinsonism
- --deep brain stimulation
- --a history of cancer within the past 5 years
- --uncontrolled diabetes

Potential participants will be screened in more detail to check whether or not they are likely to be eligible before participating in the study.

What is required of the participants?

Participants are required to make 10 visits to the study site over 34 weeks (approximately 8 months). In addition to taking the required dose (of the placebo or active compound), participants will undergo a medical history, a physical exam, lab tests (blood/urine) and various assessments related to the progression of Parkinson's. Participants will be asked to report any adverse effects they might experience during the study trial. This information will be explained in more detail at the screening visit.

IMPORTANT NOTE: Participants may discontinue the study at any time. Opting out of the study will not impact future management of the participant's Parkinson's symptoms.

How large is the study?

The study is seeking over 400 participants from sites in several countries including the United States, Canada and Europe. In Canada, the study is seeking approximately 60 participants.

Have ethical standards been met?

This study has been approved by all the Ethics Committees of the participating sites and by Health Canada. Participants must provide written informed consent prior to beginning the study.

How is the study funded?

The sponsor company is Phytopharm plc, located in the United Kingdom.

Where are the sites in Canada?

The following chart indicates the Canadian locations, and contact information.

| Investigator | Institution | Location | Contact |
|---------------------|---|-----------------|-----------------------------|
| Dr. E. Pourcher | Clinique Sainte-Anne "Memoire et mouvement" | Quebec City, QC | (418) 692-2227 |
| Dr. F. Jacques | Clinique Neuro-Outaouais | Gatineau, QC | (819) 777-2500 Ext. 3 |
| Dr. C. Hyson | London Health Sciences Centre | London, ON | (519)685-8500 Ext. 36893 |
| Dr. D. Grimes | The Ottawa Hospital - Civic Campus | Ottawa, ON | (613) 761-4619 |
| Dr. T. Mendis | Parkinson's Neurodegenerative Disorder Clinic | Ottawa, ON | (613) 737-4440 |
| Dr. A. Rajput | Royal University Hospital | Saskatoon, SK | (306) 966-8028 |
| Dr. W. Martin | Glenrose Rehab Hospital Movement Disorder Clinic | Edmonton, AB | (780) 735-6138 |

For further information, please contact the sites directly.

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