Health Canada approves NEUPRO® (rotigotine) patch for treatment of Parkinson's disease and Restless Legs Syndrome

Novel dosage form represents new treatment for Parkinson's with efficacy in motor symptoms of the disease

OAKVILLE, ON, April 2, 2013 - UCB Canada Inc. announced today that Health Canada has approved NEUPRO® (rotigotine), the first and only non-ergolinic dopamine agonist available in a patch, to treat the signs and symptoms of idiopathic Parkinson's disease (PD) and moderate-to-severe idiopathic restless legs syndrome (RLS), also known as Willis-Ekbom disease, in adults.

NEUPRO® is the first new treatment for Parkinson's disease approved by Health Canada in five years and provides 24-hour delivery of rotigotine through the skin into the blood stream. NEUPRO® has demonstrated efficacy in managing motor symptoms associated with Parkinson's disease.

"The ability to ensure a steady 24-hour delivery of medication with NEUPRO® may help to reduce debilitating on and off symptoms which many patients experience with Parkinson's treatments," says Dr. David Grimes, Director, Parkinson's Disease and Movement Disorders Clinic at the Ottawa Hospital. "The impact of sustained symptom control in the morning and in the evening can have a substantial effect on a patient's quality of life."

UCB Canada Inc. is undertaking all measures required to supply the Canadian market with NEUPRO.

"Parkinson Society Canada is pleased to learn that Canadians living with Parkinson's now have another treatment option to help manage the symptoms of this chronic disease," says Joyce Gordon, President and CEO, Parkinson Society Canada. "With innovative therapies such as NEUPRO® and ongoing research into the causes of this disease, we will help to ensure a brighter future and better quality of life for Canadians living with Parkinson's."

Although the precise mechanisms of action of NEUPRO® as treatment for PD and RLS are unknown, as a PD treatment, the mechanism of action is thought to be related to increasing the activities of the dopamine receptors within the caudate-putamen, the region of the brain that regulates movement. Similarly, in RLS, the mechanism of action of NEUPRO® is thought to be related to its ability to stimulate dopamine receptors.

Data Demonstrated Significant Symptom Improvement for PD and RLS

The effectiveness of NEUPRO® (rotigotine) in the treatment of Parkinson's disease was evaluated in a multinational drug development program consisting of four randomized, double-blind placebo-controlled phase 3 trials. A total of seven Canadian trial sites were involved in the international studies.
In all trials, patients underwent a weekly titration of NEUPRO® in 2 mg/24 hour increments to the assigned or optimal dose.

In two trials, statistically significant improvements in the combined scores on the Unified Parkinson's Disease Rating Scale (UPDRS) were observed in early-stage PD patients receiving NEUPRO® compared to patients receiving placebo. The UPDRS is a validated multi-item rating scale intended to evaluate mentation (mental activity), activities of daily living (ADL), motor performance, and complications of therapy. The two trials measured only the ADL and motor performance sections of the UPDRS. The UPDRS contains 13 questions relating to ADL, such as speech, dressing, and cutting food with utensils, and 27 questions related to the cardinal motor symptoms in PD patients—i.e., tremor, rigidity, bradykinesia, and postural instability.

Two trials of NEUPRO® in patients with advanced-stage PD examined change from baseline in "off" time, periods when the effectiveness of medication wears off and PD symptoms return. Statistically significant changes in off-times were observed in advanced-stage PD patients receiving NEUPRO® compared with those who received placebo.

The effectiveness of NEUPRO® in the treatment of Restless Legs Syndrome (RLS) was evaluated in two fixed-dose, randomized, double-blind, placebo-controlled phase 3 trials with maintenance periods of 6 months duration. Patients received NEUPRO® doses ranging from 0.5 mg/24 hours to 3 mg/24 hours, or placebo, once daily. Statistically significant improvements in sum scores on the International RLS Rating Scale (IRLS Scale) and the Clinical Global Impression - Improvement (CGI-I) assessment were observed in RLS patients receiving NEUPRO® compared with those receiving placebo. The IRLS Scale contains 10 items designed to assess the severity of sensory and motor symptoms, sleep disturbance, daytime somnolence, and impact on activities of daily living and mood associated with RLS. The CGI-I is designed to clinically assess RLS symptoms on a 7-point scale.

In clinical trials, treatment emergent adverse events reported in more than 10% of patients treated with NEUPRO® for Parkinson's disease included nausea, vomiting, dizziness, somnolence, application site reactions and headache. Treatment emergent adverse events reported in more than 10% of patients treated with NEUPRO® for Restless Legs Syndrome, included nausea, application site reactions, fatigue and headache.

**About Parkinson's disease**

Parkinson's disease (PD) is a chronic, degenerative neurological disease which affects approximately 100,000 Canadians. PD develops with the loss of nerve cells in the brain that produce a chemical called dopamine. The symptoms of PD can have an impact on many dimensions of patients' lives. As dopamine levels fall, movement (motor) symptoms—tremors (uncontrollable shaking), rigidity (stiffness or muscle tensing) and bradykinesia (slowness and loss of spontaneous movement) — can progress, along with the underlying symptoms of PD, which are less well recognized and may be under-treated.

**About Restless Legs Syndrome**

Restless Legs Syndrome (RLS) is a neurological disorder characterized by unpleasant sensations in the legs and an uncontrollable urge to move to gain relief. Over 80% of people with RLS also have periodic
limb movement disorder (PLMD), which causes rhythmic limb movements during sleep. RLS affects between three and 10 per cent of the population to some extent. Some estimates are much higher because RLS is thought to be underdiagnosed, and in some cases, misdiagnosed. Most people with RLS have difficulty falling asleep and staying asleep. Daytime symptoms of RLS, such as inability to sit still and involuntary leg jerks, are increasingly recognized. While the underlying pathophysiology of RLS is not fully understood, it is thought to involve central dopamine systems. Recent neuroimaging data suggest that RLS patients may carry an abnormality in dopamine transport that can be visualized both day and night. RLS can cause exhaustion and daytime fatigue, and may affect work and personal relationships. Patients with moderate-to-severe RLS are often unable to concentrate, have impaired memory, or fail to accomplish daily tasks. These patients may require long-term treatment for their RLS symptoms.

About UCB Canada Inc.
Inspired by patients and driven by science, UCB Canada Inc. is a biopharmaceutical company focused on the discovery and development of innovative medicines and solutions to transform the lives of people living with severe auto-immune and central nervous system diseases. For more information, please consult www.ucb.com/worldwide/canada.

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