Neupro® Filed in Europe for the Treatment of Restless Legs Syndrome

Application for marketing authorisation for the use of Neupro® (*rotigotine* transdermal patch) in the treatment of moderate-to-severe Restless Legs Syndrome (RLS) accepted for filing by the European Medicines Agency (EMEA).

Brussels, BELGIUM, December 5, 2007 at 7:00 am CET – UCB announced today that the application for marketing authorization for the use of Neupro® in the treatment of moderate-to-severe Restless Legs Syndrome (RLS) has been accepted for filing by the European Medicines Agency (EMEA). Neupro® is a once-daily patch designed to provide continuous drug delivery over a 24 hour period. Restless Legs Syndrome is a chronic neurological disorder that affects between three and ten per cent of the population.[1]

"This new filing for Neupro® reflects UCB's commitment to finding innovative medicines for conditions where there is a continuing need for alternative treatment," commented Troy Cox, President CNS Operations, UCB.

The filing is based on the results of two fixed-dose, randomized, double-blind, placebo-controlled efficacy and safety studies that evaluated *rotigotine* for the treatment of moderate-to-severe idiopathic RLS in approximately 1,000 patients over six months.[2,3] In these trials, *rotigotine* produced statistically significant reductions in RLS symptoms compared to placebo and was generally well-tolerated.[2,3] The efficacy of *rotigotine* was evaluated by monitoring the International Restless Legs Severity Scale (IRLS), a clinician-administered tool considered to be the best scale for evaluating the severity and frequency of RLS symptoms and the degree to which they affect sleep and daily life.[4] The most frequently reported adverse events associated with *rotigotine* in these studies were application site reactions, nausea, dizziness, somnolence and headache.[2,3]

Neupro® is already approved in Europe and the U.S. for the treatment of the signs and symptoms of early-stage idiopathic Parkinson's Disease as monotherapy[5,6], and in Europe as adjunctive therapy with levodopa for advanced-stage Parkinson's disease.[5]

About Restless Legs Syndrome [1,7,8,9]***:*** *Restless legs syndrome (RLS) is a chronic neurological disorder that affects between 3 and 10% of the population. It is characterized by unpleasant feelings in the legs and an irresistible urge to move in order to relieve the discomfort. RLS sensations are frequently described as tingling, burning, tugging, gnawing and pulling. The exact cause of RLS is not known; however, recent clinical research has linked certain genes to RLS, suggesting that the disorder is biologically based.*
Symptoms of RLS typically appear during periods of rest and inactivity, particularly in the evenings and at night. This can make it difficult to fall asleep and stay asleep, thus preventing recuperative sleep and often leading to daytime fatigue and reduced alertness. While RLS symptoms are generally most pronounced in the evening and while at rest, other periods of inactivity, such as long flights, car trips and sitting in a theatre or cinema, can also trigger symptoms.

About Neupro® in Europe [5,10]***:*** *In Europe, Neupro® is indicated for the treatment of the signs and symptoms of early-stage idiopathic Parkinson's disease as monotherapy and in combination with levodopa for advanced stage Parkinson's disease.*
Neupro® delivers the dopamine agonist, rotigotine, directly from a patch into the bloodstream, through the skin. Rotigotine is a drug that mimics dopamine, a chemical messenger that transmits impulses between nerve cells in the brain to produce smooth, coordinated movement. Neupro® offers once-daily dosing and a good tolerability profile.

Important Safety Information[5]
Neupro® has been associated with somnolence including excessive daytime somnolence and sudden sleep onset episodes. In isolated cases "sudden onset of sleep" occurred while driving and resulted in motor vehicle accidents. Sudden onset of sleep during daily activities, in some cases without awareness of any warning signs has been reported.
It is recommended to monitor blood pressure, especially at the beginning of treatment, due to the general risk of orthostatic hypotension associated with dopaminergic therapy.
Hallucinations have been reported and patients should be warned that hallucinations can occur.
Caution is advised when treating patients with severe hepatic impairment which may result in lower rotigotine clearance.
Adverse drug reactions (ADRs) reported in more than 10% of patients treated with Neupro® transdermal patch are nausea, dizziness, somnolence and application site reactions. Application site reactions are usually mild or moderate in intensity and it is recommended that the application site should be rotated on a daily basis.

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4. *Decision Resources. "Restless Legs Syndrome" Cognos Study #3. November 2006*
5. *Neupro® Prescribing Information (EU)*
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About UCB

UCB, Brussels, Belgium (www.ucb-group.com) is a global leader in the biopharmaceutical industry dedicated to the research, development and commercialization of innovative pharmaceutical and biotechnology products in the fields of central nervous system disorders, allergy/respiratory diseases, immune and inflammatory disorders and oncology. UCB focuses on securing a leading position in severe disease categories. Employing more than 10,000 people in over 40 countries, UCB achieved revenue of 3.5 billion euro in 2006 on a pro forma basis. UCB S.A. is listed on the Euronext Brussels Exchange and, through its affiliate, owns approx. 89% of the shares of SCHWARZ PHARMA AG. SCHWARZ PHARMA (Monheim, Germany) is a member of the UCB Group.

Forward looking statement

This press release contains forward-looking statements based on current plans, estimates and beliefs of management. Such statements are subject to risks and uncertainties that may cause actual results to be materially different from those that may be implied by such forward-looking statements contained in this press release. Important factors that could result in such differences include: changes in general economic, business and competitive conditions, effects of future judicial decisions, changes in regulation, exchange rate fluctuations and hiring and retention of its employees.