Neupro® Filed with the FDA for the Treatment of Restless Legs Syndrome

The U.S. Food and Drug Administration (FDA) has accepted for filing the Supplemental New Drug Application (sNDA) for the use of Neupro® (*Rotigotine* Transdermal System) as a treatment for moderate-to-severe Restless Legs Syndrome (RLS).

Brussels, December 13, 2007 at 7:00 am CET – UCB announced today that the supplemental New Drug Application (sNDA) for the use of Neupro® as a treatment for moderate-to-severe restless legs syndrome (RLS) has been accepted for filing by the U.S. Food and Drug Administration (FDA). Neupro® is a patch designed to provide continuous drug delivery. Restless Legs Syndrome is a chronic neurological disorder that affects between three and ten per cent of the population.[1]

"The acceptance of the sNDA underscores our ongoing commitment to provide innovative therapies for patients living with debilitating Central Nervous System disorders," said Troy Cox, President CNS Operations, UCB.

The submission is based on 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. In these trials, rotigotine produced statistically significant reductions in RLS symptoms 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]

"This chronic condition can be serious and even debilitating with many patients requiring treatment that offers sustained symptom control," said *rotigotine* study investigator Arthur S. Walters, MD, Professor, Department of Neuroscience, Seton Hall University School of Graduate Medical Education, and Director of the Center for Sleep Disorders Treatment, Research and Education at the New Jersey Neuroscience Institute at JFK Medical Center. "These study results showed that *rotigotine* significantly improved symptoms of restless legs syndrome throughout the six month trial period."

In July 2007 Neupro® was launched in the United States for the treatment of the signs and symptoms of early-stage idiopathic Parkinson's disease.[5] In Europe, Neupro® is indicated for the treatment of the signs and symptoms of early-stage idiopathic Parkinson's disease as monotherapy and as adjunctive therapy with levodopa in advanced stage Parkinson's disease.[6]

About Restless Legs Syndrome [1,7,8,9]**:** Restless legs syndrome (RLS) is a chronic neurological disorder that affects between 3 and 10 percent 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 movie theater, can also trigger symptoms.

About Neupro® in the USA [5,10]**:** In the USA, Neupro® is indicated for the treatment of the signs and symptoms of early-stage idiopathic Parkinson's disease as monotherapy. Neupro® delivers the dopamine agonist, *rotigotine*, directly from a patch into the bloodstream, through the skin and offers stable, continuous delivery of *rotigotine* 24 hours-a-day. *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]**

Some patients treated with Neupro® reported falling asleep while engaged in activities of daily living, including operation of motor vehicles, which sometimes resulted in accidents. Some patients perceived no warning signs, such as excessive drowsiness. Hallucinations were reported in 2.0% of patients treated with Neupro® compared to 0.7% of patients on placebo. Neupro® should be used with caution in patients with cardiovascular disease because of the potential for symptomatic hypotension, syncope, elevated heart rate, elevated blood pressure, fluid retention, and/or weight gain. All Parkinson's disease patients are at a higher risk for melanoma and should be monitored regularly. The most commonly reported side effects (≥5%) in clinical trials were nausea, application site reactions, somnolence, dizziness, headache, vomiting, and insomnia. Some subjects who received Neupro® experienced a decline in blood hemoglobin levels (about 2% relative to subjects who received placebo). It is not known whether this change is readily reversible with discontinuation of Neupro®. For full prescribing information, please visit www.neupro.com.

References

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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 commercialisation 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 around 12,000 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.

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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.