Neupro® Filed with the FDA for the Treatment of Advanced-Stage Parkinson's Disease

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 adjunctive therapy with levodopa in adult patients with advanced-stage Parkinson's disease

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 adjunctive therapy with levodopa in adult patients with advanced-stage Parkinson's disease has been accepted for filing by the U.S. Food and Drug Administration (FDA).

The FDA has already approved Neupro® for the treatment of the signs and symptoms of early-stage idiopathic Parkinson's disease and the drug has been commercially available in the United States since July 2007.[1]

"We are excited that patients with all stages of Parkinson's disease may soon benefit from Neupro®'s 24-hour continuous drug delivery," said Troy Cox, President CNS Operations, UCB.

The sNDA is based on efficacy and safety data in more than 670 patients with advanced-stage Parkinson's disease who were treated with rotigotine in three double-blind, placebo-controlled clinical trials. These studies demonstrated that rotigotine, as adjunctive therapy to levodopa in patients with advanced-stage Parkinson's disease, showed clinically relevant reductions in "off" time (periods where the effectiveness of medications wear off and Parkinson's symptoms return) and favorable increases in "on" time without troublesome dyskinesia (fragmented or jerky movements). The most frequently-reported adverse events in rotigotine clinical trials included application site reactions, nausea, vomiting, dizziness, somnolence and dyskinesia. [2,3,4]

"As these clinical studies have shown, continuous delivery of rotigotine in a transdermal form can improve control of 'off' time in advanced-stage Parkinson's patients throughout the day and night. Once-daily dosing may improve compliance over medications that require several daily doses," said Peter A. LeWitt, MD, Professor of Neurology, Wayne State School of Medicine, and Director of the Parkinson's Disease and Movement Disorders Program, Henry Ford Hospital in Southfield, Michigan.

In Europe, Neupro® is already 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.[5]

About Parkinson's Disease [6,7,8,9]*: Parkinson's disease is a progressive disorder of the central nervous system. The patients - roughly four million worldwide, including approximately one million people in the United States - suffer primarily from a lack of dopamine, a messenger substance in the central nervous system, which is responsible for the coordination of movement. As a result of this shortage, patients are no longer able to control their movements reliably. Dopamine agonists are drugs that attempt to compensate for this lack of dopamine.*

About Neupro® in the USA [1,6]***:*** *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[1]

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, especially those at risk for 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 in clinical trials (≥5%) 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

1. *Neupro® Prescribing Information (US). (available at http://www.neupro.com/USHome.html)*
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4. *LeWitt, P., Lyons, K., Pahwa, R., Boroojerdi, B., et. al for the SP650 Study Group. Transdermal Rotigotine in Combination with Levodopa in the Treatment of Advanced Parkinson's Patients. Poster Presentation, 132nd Annual Meeting of the American Neurological Association, October 7-10, 2007.*
5. *Neupro® Package Leaflet (EU).*
6. *Parkinson's Disease: Dopamine Agonists. Schwarz Pharma. (available at http://www.parkinsons-disease.com/products/n28/dopamine%20agonists)*
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9. *Parkinson's Disease: Cause of Parkinson's Disease. Schwarz Pharma. (available at http://www.parkinsons-disease.com/products/n18/Cause_of_the_disease/)*

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 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.