



## UCB receives CHMP positive opinion on bringing Neupro® back to all patients in Europe

- CHMP recommends lifting of treatment restrictions for Neupro® in Europe
- Recommends allowing Neupro® to be available to all patients with Parkinson's disease
- Recommends allowing Neupro® to be launched for the treatment of moderate to severe RLS

**Brussels (Belgium), 29 May 2009 - press release, regulated information** - UCB announced today that the European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) has issued a positive opinion recommending that the European Commission lifts the treatment restrictions for Neupro® (rotigotine transdermal patch) in Europe.

"The positive opinion of the EMA's CHMP is an important step towards making Neupro® available to all patients with Parkinson's disease and to patients with Restless Legs Syndrome" said Troy Cox, Senior Vice President CNS Operations, UCB. "UCB is proud of its record of providing innovative treatment solutions for conditions that have a real unmet need. With Neupro® we have a 24 hour, continuous drug delivery treatment that offers patients improvements in their symptoms and benefits to their everyday lives."

In June 2008, Neupro® supply in Europe was limited to patients already established on the drug. UCB has fully implemented a cold-chain storage and distribution system and all stocks of Neupro® (2 mg/24 h, 4 mg/24 h, 6 mg/24 h and 8 mg/24 h) have been replaced with product that is refrigerated from manufacturer to patient. Pending final approval of the European Commission, Neupro® will be available to all patients with Parkinson's disease in Europe.

### **Neupro® in Parkinson's Disease**

Parkinson's disease affects approx. three million patients in the seven major markets (U.S., Japan, Germany, UK, France, Italy and Spain). Neupro® provides statistically significant and clinically relevant improvements in movement and ability to carry out everyday activities in people with early stage Parkinson's disease and significantly reduces 'off' time and increases 'on' time in people with later stage Parkinson's disease. Formulated as a once-a-day transdermal patch, Neupro® continuous drug delivery provides stable drug levels in the bloodstream.

### **Neupro® in RLS**

In August 2008, the European Commission approved Neupro® for the symptomatic treatment of idiopathic moderate to severe Restless Legs Syndrome (RLS) in adults.



Pending final approval of the European Commission, the UK and Germany will be the first European countries to launch Neupro® (1 mg/24 h, 2 mg/24h and 3 mg/24 h) in this new indication.

RLS affects between three and ten per cent of the population to some extent. In a clinical trial of 458 patients with moderate to severe RLS, Neupro® (1 mg/24 h, 2 mg/24 h and 3 mg/24 h dose) proved more efficacious than placebo in relieving bedtime, night and daytime symptoms in patients over a six month treatment period. Neupro® was shown to reduce symptoms by  $\geq 50\%$  in over half of patients (54.2%) compared to symptom reduction in approximately one third (29.9%) of patients on placebo. In addition more patients receiving Neupro® (3 mg/24h) achieved clinical remission (47.3% vs. 22.8% placebo) and symptom freedom (31.3% vs. 12.3% placebo).

#### **Further information**

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#### **Notes to Editors**

##### **About Parkinson's Disease**

Parkinson's disease is a chronic, degenerative neurological disease which affects approximately six million people worldwide. Parkinson's disease develops with the loss of nerve cells in the brain which produce a chemical called dopamine. The symptoms of Parkinson's disease develop gradually as levels of dopamine fall and include: tremors (uncontrollable shaking), rigidity (stiffness or tensing of the muscles) and bradykinesia (slowness of movement, and loss of spontaneous movement). Parkinson's disease is often divided into two parts; early stage and later stage disease.

##### **About Restless Legs Syndrome**

RLS is a lifelong condition, the symptoms of which may gradually worsen with age. RLS affects between 3 and 10% of the population to some extent, causing sensations such as tingling, burning, tugging, gnawing and pulling, and ranging in severity from uncomfortable to irritating and at times painful. Symptoms frequently occur during periods of rest and inactivity such as night time. If left untreated, Restless Legs Syndrome can cause exhaustion and negatively impact quality of life.

##### **About Neupro® in Europe**

Neupro® is indicated in Europe for the symptomatic treatment of moderate to severe idiopathic restless legs syndrome in adults, and for the treatment of the signs and symptoms of early-stage idiopathic Parkinson's disease, as monotherapy or in combination with levodopa over the course of the disease through to late stages when the effect of levodopa wears off or becomes inconsistent and fluctuations of the therapeutic effect occurs.

##### **Neupro® Important Safety Information**

Adverse drug reactions reported in more than 10% of RLS patients treated with Neupro® (rotigotine transdermal patch) are nausea, application site reactions, fatigue and headache. Adverse drug reactions reported in more than 10% of Parkinson's patients treated with Neupro® are nausea, dizziness, somnolence and application site reactions. The incidence of some dopaminergic adverse events, such as hallucinations, dyskinesia, and peripheral oedema generally is higher when given in



combination with L-dopa in Parkinson's patients. This should be considered when prescribing rotigotine.

*Neupro® is contraindicated in case of hypersensitivity to the active substance or to any of its excipients, and in case of magnetic resonance imaging or cardioversion. The backing layer of Neupro® contains aluminium. To avoid skin burns, Neupro® should be removed if the patient has to undergo MRI or cardioversion. 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. Patients treated with dopamine agonists including Neupro®, have been reported as exhibiting signs of pathological gambling, increased libido and hypersexuality, generally reversible upon reduction of the dose or treatment discontinuation.*

*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 informed that hallucinations can occur.*

*If there is a skin rash or irritation from the transdermal system, direct sunlight on the area should be avoided until the skin heals. Exposure could lead to changes in the skin color.*

*If a generalised skin reaction (e.g. allergic rash, including erythematous, macular, papular rash or pruritus) associated with the use of Neupro® is observed, Neupro® should be discontinued.*

*Cases of fibrotic complications: retroperitoneal fibrosis, pulmonary infiltrates, pleural effusion, pleural thickening, pericarditis and cardiac valvulopathy have been reported in some patients treated with ergot-derived dopaminergic agents. While these complications may resolve when treatment is discontinued, complete resolution does not always occur.*

*All Neupro® supply should be stored in a refrigerator. There is no need for patients to transport Neupro® patches in special containers and they must not be stored in a freezer compartment.*

*Refer to the European Summary of Product Characteristics for full prescribing information.*  
<http://www.emea.europa.eu/humandocs/PDFs/EPAR/neupro/H-626-PI-en.pdf>

#### **Neupro® in the U.S.**

*UCB recalled Neupro® from the U.S. market in April 2008 after ongoing monitoring revealed that specific batches of Neupro® had deviated from their approved specification. UCB is working with the U.S. Food and Drug Administration (FDA) so that Neupro® can be available to patients with early-stage Parkinson's disease as soon as possible.*

#### **About UCB**

*UCB, Brussels, Belgium ([www.ucb.com](http://www.ucb.com)) is a biopharmaceutical company dedicated to the research, development and commercialization of innovative medicines with a focus on the fields of central nervous system and immunology disorders. Employing more than 10 000 people in over 40 countries, UCB produced revenue of 3.6 billion euro in 2008. UCB is listed on Euronext Brussels (symbol: UCB).*

#### **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.*