

UCB brings Neupro[®] back to all patients in Europe

- European Commission lifts the treatment restrictions for Neupro[®]
- Neupro[®] can be prescribed for all patients in accordance with the approved indications
 - Neupro[®] available again to all patients with Parkinson's disease
 - Neupro[®] newly available to adult patients with moderate to severe Restless Legs Syndrome

Brussels (Belgium), **29 June 2009 – press release**, **regulated information –** UCB announced today that Neupro[®] (*rotigotine* transdermal patch) can now be prescribed to all patients with idiopathic Parkinson's disease in Europe and is newly available for the symptomatic treatment of moderate to severe idiopathic Restless Legs Syndrome (RLS) in adults. This follows the decision of the European Commission to lift treatment restrictions on Neupro[®] in line with the recommendation of the European Medicines Agency (EMEA), issued on 29 May 2009.

"We are delighted that all patients with Parkinson's disease in Europe can once again benefit from continuous drug delivery and the improvement in symptoms that is offered with Neupro[®] and that, for the first time, people with RLS in Europe will also experience the advantages of this important treatment," said Troy Cox, Senior Vice President CNS Operations, UCB.

Since June 2008, Neupro[®] supply in Europe has been limited to patients already established on the drug while a new cold-chain storage and distribution system was developed to meet the need for refrigeration of the product from manufacturer to patient. Following full implementation of this system, refrigerated stocks of Neupro[®] are available in all doses so Neupro[®] can be prescribed by European physicians for all patients with idiopathic Parkinson's disease.

Neupro[®] in Parkinson's disease

Parkinson's disease affects over six million people worldwide and approximately three million patients in the seven major markets (U.S., Japan, Germany, UK, France, Italy and Spain). Formulated as a once-a-day transdermal patch, Neupro[®] continuous drug delivery provides stable drug levels in the bloodstream. 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. Neupro[®] is generally well-tolerated. Adverse drug reactions reported in more than 10% of Parkinson's patients treated with Neupro[®] are nausea, dizziness, somnolence and application site reactions.

Neupro[®] in RLS

In August 2008, the European Commission approved Neupro[®] for the symptomatic treatment of idiopathic moderate to severe RLS in adults. The UK and Germany are the



first European countries to launch Neupro[®] (1 mg/24 h, 2 mg/24 h and 3 mg/24 h) in this new indication.

RLS affects between 3 and 10% 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/24 h) achieved clinical remission (47.3% vs. 22.8% placebo) and symptom freedom (31.3% vs. 12.3% placebo).

"We look forward to having Neupro[®] available as a new treatment option for RLS patients. The results of this *rotigotine* trial demonstrated efficacy, increased opportunity for symptom freedom in moderate to severely affected RLS patients and improvements to patients' quality of life" said Dr Claudia Trenkwalder from the Paracelsus-Elena Hospital, Kassel, Germany and lead investigator of the study.

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 per cent 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 approved 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.

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

About 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 earlystage Parkinson's disease as soon as possible.

About UCB

UCB, Brussels, Belgium (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 approximately 10 000 people in over 40 countries, UCB achieved revenues 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.