



## **FOR THE ATTENTION OF EUROPEAN ACCREDITED MEDICAL WRITERS**

### **Clinical data presented at International Congress showed treatment with Neupro<sup>®</sup> (rotigotine) significantly improved early morning akinesia and was generally well tolerated over four years**

- *Data presented at the 13<sup>th</sup> International Congress of Parkinson's Disease and Movement Disorders*
- *Long-term treatment with rotigotine was generally well tolerated in patients with early stage Parkinson's disease (up to four years)<sup>1</sup>*
- *Treatment with rotigotine improved early morning akinesia in patients with advanced Parkinson's disease<sup>2</sup>*

**Brussels, BELGIUM– June 12, 2009 at 0700 CET** — Clinical data presented this week at the 13<sup>th</sup> International Congress of Parkinson's Disease and Movement Disorders in Paris, France showed rotigotine improved early morning akinesia in patients with advanced Parkinson's disease.<sup>2</sup> Data also demonstrated the tolerability of rotigotine over four years of treatment in patients with early stage Parkinson's disease.<sup>1</sup>

Neupro<sup>®</sup> (rotigotine) is approved in Europe 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 occur.<sup>3</sup>

#### **Long-term treatment with rotigotine (up to four years) was generally well-tolerated in patients with early stage Parkinson's disease<sup>1</sup>**

An open-label extension study of patients with early-stage Parkinson's disease showed that over a four year maintenance period, rotigotine showed low rates of discontinuations and a low incidence of dyskinesia.

The study comprised 137 patients randomized to rotigotine (2 mg/24 h) and 79 randomised to placebo. The majority (63%) remained in the study over 4 years of open-label maintenance. Discontinuations due to treatment-related adverse events were low (17%). Most withdrawals occurred within the first 12 months with the most common occurrences including application site erythema (14%), pruritus (9%), inflammation (7%) and skin reactions (5%).



The adverse events most frequently reported including somnolence (49%), peripheral edema (34%), fall (28%), nausea (25%) and dizziness (25%).

Thirty four patients (16%) experienced dyskinesias. In 28 of the 34 reported cases, dyskinesia developed after initiation of levodopa.

### **Adjunctive rotigotine improved early morning akinesia in patients with advanced Parkinson's disease<sup>2</sup>**

Analysis of patient diaries from two large 6-month, randomized, double blind, placebo-controlled trials (PREFER and CLEOPATRA-PD) showed adjunctive rotigotine improved early-morning akinesia in patients with advanced Parkinson's disease compared with placebo.

In PREFER, analysis comprised 222 patients randomised to rotigotine and 119 randomised to placebo. The proportion of patients in the rotigotine treated group awakening in an 'off' state was reduced by 28.8% (8 mg/24 h) and 22.6% (12 mg/24 h) compared to 9.1% with placebo.

In CLEOPATRA-PD, 200 rotigotine-treated patients and 100 placebo-treated patients were analysed. The proportion of patients awakening in an 'off' state decreased by 22.6% for the rotigotine-treated group ( $\leq 16$  mg/24 h) versus 10.7% with placebo. In addition, the proportion of patients awakening in an 'on' state without troublesome dyskinesia increased by 23.3% with rotigotine ( $\leq 16$  mg/24 h) versus 11.1% with placebo.

#### **‡Notes to Editors**

In June 2008 Neupro<sup>®</sup> (rotigotine) supply in Europe was limited to patients already established on the drug after ongoing monitoring of marketed product revealed the appearance of crystals in some patches.

UCB has fully implemented a cold-chain storage and distribution system and all stocks of Neupro<sup>®</sup> (rotigotine) have been replaced with product that is refrigerated from manufacturer to patient. On 29<sup>th</sup> May 2009 the European Medicines Agency recommended that the treatment restrictions for Neupro<sup>®</sup> (rotigotine) in Europe be lifted. This recommendation is now passed to the European Commission for endorsement. Once this recommendation is endorsed by the European Commission, doctors in the European Union will then be able to prescribe Neupro<sup>®</sup> (rotigotine) to patients in accordance with the approved product information.

#### **About Neupro<sup>®</sup> (rotigotine) in Europe<sup>3</sup>**

Neupro<sup>®</sup> (1 mg/24 h, 2 mg/24 h and 3 mg/24 h) is approved in Europe for the symptomatic treatment of moderate to severe idiopathic restless legs syndrome in adults<sup>4</sup>. Neupro<sup>®</sup> (rotigotine) (2 mg/24 h, 4 mg/24 h, 6 mg/24 h and 8 mg/24 h) is approved in Europe 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® (rotigotine) Important Safety Information<sup>3</sup>**

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® (rotigotine) 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® (rotigotine) 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® (rotigotine) contains aluminium. To avoid skin burns, Neupro® (rotigotine) should be removed if the patient has to undergo MRI or cardioversion. Neupro® (rotigotine) has been associated with somnolence including excessive daytime somnolence and sudden sleep onset episodes.

Neupro® (rotigotine) 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® (rotigotine), 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® (rotigotine) is observed, Neupro® (rotigotine) 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® (rotigotine) supply should be stored in a refrigerator. There is no need for patients to transport Neupro® (rotigotine) patches in special containers and they must not be stored in a freezer compartment.



¥The indication for the symptomatic treatment of moderate to severe idiopathic restless legs syndrome in adults is not available in all countries

#### **About Neupro® (rotigotine) in the U.S.**

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

#### **Further information**

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#### **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 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.*

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