



## **Extensive Neupro® (Rotigotine Transdermal System) data to be presented at the 62<sup>nd</sup> American Academy of Neurology Meeting in Toronto, Canada**

- New data from RECOVER study on effects of rotigotine on both motor and non-motor symptoms of Parkinson's disease
- New 5-year safety and efficacy data on rotigotine in Restless Legs Syndrome

**Atlanta, April 8, 2010** – Extensive new data on rotigotine will be presented at the 62<sup>nd</sup> American Academy of Neurology annual meeting in Toronto, Canada between April 10<sup>th</sup> and 17<sup>th</sup>, 2010.

At a series of oral and poster presentations, leading international investigators will report the latest data on rotigotine in all stages of Parkinson's disease and in moderate to severe Restless Legs Syndrome (RLS).

### **Oral presentations**

#### **SP710 (5 year) Long-term Safety and Efficacy of Rotigotine in Patients with Idiopathic RLS: 5-year Results from a Prospective Multinational Open-label Follow-up Study**

Högl B, Trenkwalder C, **Garcia-Borreguero D**, Kohnen R, Poewe W, Stiasny-Kolster K, Bauer L, Fichtner A, Schollmayer E, Oertel W for the SP710 study group

The presentation will report on the final 5-year analysis from a prospective follow-up of a placebo-controlled phase II trial with rotigotine in patients with moderate to severe RLS.

**Date:** Tuesday, April 13, 2010  
**Scientific Session #:** S04.006: Sleep Disorders  
**Authors present:** 3:00 PM EDT  
**Place:** Constitution Hall 107



## **RECOVER: Effect of Rotigotine on Non-motor Symptoms in Subjects with Idiopathic Parkinson's Disease**

**Chaudhuri KR**, Rudzinska M, Kies B, Fine J, Hill DL, Anderson T, Surmann E, Whitesides J, Boroojerdi B and Trenkwalder C, on behalf of the RECOVER study group

The presentation will report on the effect of rotigotine on non-motor symptoms of Parkinson's disease, such as sleep, mood and cognition.

**Date:** Wednesday, April 14, 2010  
**Scientific Session #:** S23.006: Movement Disorders: Parkinson's Disease/Non-Motor  
**Authors present:** 3:15 PM EDT  
**Place:** Room 718AB

### **Poster presentations**

## **RECOVER: Effect of Rotigotine on Sleep Quality and Control of Early Morning Motor Function in Subjects with Idiopathic Parkinson's Disease**

The presentation will report on the effects of rotigotine on movement and sleep problems in people with Parkinson's disease.

**Kies B**, Chaudhuri KR, Anderson T, Fine J, Hill DL, Rudzinska M, Surmann E, Whitesides J, Boroojerdi B, Trenkwalder C on behalf of the RECOVER Study Group

**Date:** Tuesday, April 13, 2010  
**Poster #:** P01.240: Movement Disorders: Parkinson's Disease/Non-Motor Symptoms  
**Authors present:** 7:30 AM EDT  
**Place:** Room 808

## **Long-Term Treatment of Advanced Parkinson's Disease With Rotigotine**

**LeWitt P**, Boroojerdi B, Poewe W, on behalf of the SP516 and SP715 study groups

The presentation will report on the long-term efficacy (over 4-6 years) of rotigotine in people with advanced Parkinson's disease.

**Date:** Wednesday, April 14, 2010  
**Poster #:** P04.131: Movement Disorders: Parkinson's Disease: Treatment  
**Authors present:** 6:00 PM EDT  
**Place:** Room 808



## **Open-Label Extension to the Double-Blind SP512 Trial to Assess the Safety of Long-Term Treatment of Rotigotine in Subjects With Early-Stage Idiopathic Parkinson's Disease**

**Watts R**, Boroojerdi B, Jankovic J, on behalf of the SP702 study group

The presentation will report on the long-term efficacy and tolerability of rotigotine in early stage Parkinson's disease.

**Date:** Wednesday, April 14, 2010  
**Poster #:** P04.133: Movement Disorders: Parkinson's Disease: Treatment  
**Authors present:** 6:00 PM EDT  
**Place:** Room 808

### ***For further information***

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***Will be available on site at the meeting***

### **About Neupro® in the U.S.**

Neupro® (Rotigotine Transdermal System) is indicated in the U.S. for the treatment of the signs and symptoms of early-stage idiopathic Parkinson's disease.

In April 2008, UCB recalled Neupro® from the U.S. market after ongoing monitoring revealed that specific batches of Neupro® had deviated from their approved specification. Neupro® is currently not available in the U.S. UCB is working with the U.S. FDA so that Neupro® can be available to patients with early-stage Parkinson's disease as soon as possible.

### **Important Safety Information – U.S.**

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® contains metabisulfite. 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 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®.

### **About Neupro® in Europe**



Neupro<sup>®</sup> (rotigotine) is approved in the European Union for the treatment of the signs and symptoms of early-stage idiopathic Parkinson's disease, as monotherapy (i.e. without levodopa) or in combination with levodopa, i.e. 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<sup>®</sup> is also approved in the European Union for the symptomatic treatment of moderate to severe idiopathic restless legs syndrome in adults.

### **Neupro<sup>®</sup> in Europe Important Safety Information**

Neupro<sup>®</sup> is contraindicated in case of hypersensitivity to the active substance or to any of its excipients, and in case of magnetic resonance imaging (MRI) or cardioversion. Neupro<sup>®</sup> should be removed if the patient has to undergo MRI or cardioversion.

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.

Neupro<sup>®</sup> has been associated with somnolence episodes of sudden sleep onset episodes. Patients treated with dopamine agonists including Neupro<sup>®</sup>, have been reported as exhibiting signs of pathological gambling, increased libido and hypersexuality.

Symptoms suggestive of neuroleptic malignant syndrome have been reported with abrupt withdrawal of dopaminergic therapy. Therefore it is recommended to taper treatment.

Neupro<sup>®</sup> contains sodium metabisulphite, a sulphite that may cause allergic-type reactions including anaphylactic symptoms and life threatening or less severe asthmatic episodes in certain susceptible people.

Hallucinations have been reported, and patients should be informed that hallucinations can occur.

Cases of cardiopulmonary fibrotic complications have been reported in some patients treated with ergot-derived dopaminergic agents. Neuroleptics given as antiemetic should not be given to patients taking dopamine agonists. Ophthalmologic monitoring is recommended at regular intervals or if vision abnormalities occur.

External heat, from any source should not be applied to the area of the patch. Exposure of a skin rash or irritation to direct sunlight could lead to changes in the skin color. If a generalized skin reaction (e.g. allergic rash) associated with the use of Neupro<sup>®</sup> is observed, Neupro<sup>®</sup> should be discontinued.

Caution is advised when treating patients with severe hepatic impairment or acute worsening of renal function, a dose reduction might be needed.

The incidence of some dopaminergic adverse events, such as hallucinations, dyskinesia, and peripheral oedema generally is higher when given in combination with L-dopa. This should be considered when prescribing Neupro<sup>®</sup>.



Neupro<sup>®</sup> should not be used during pregnancy. Breast-feeding should be discontinued.

Augmentation may occur in Restless Legs Syndrome patients. Augmentation refers to the earlier onset of symptoms in the evening (or early afternoon), increase in severity of symptoms, and spread of symptoms to involve other body parts.

Adverse drug reactions reported in more than 10% of Parkinson's patients treated with Neupro<sup>®</sup> are nausea, vomiting, application site reactions, somnolence, dizziness and headache.

Adverse drug reactions reported in more than 10% of RLS patients treated with Neupro<sup>®</sup> are nausea, application site reactions, asthenic conditions and headache.

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

Please refer to the European Summary of Product Characteristics for full prescribing information (Approved 15<sup>th</sup> March 2010): <http://www.emea.europa.eu/humandocs/PDFs/EPAR/neupro/emea-combined-h626en.pdf>

**About UCB**

*UCB, Brussels, Belgium 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 9 000 people in over 40 countries, UCB produced revenue of EUR 3.1 billion in 2009. 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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