



## Neupro<sup>®</sup> (rotigotine transdermal patch) approved in Japan for Parkinson's disease and Restless Legs Syndrome

- *Otsuka Pharmaceutical has the exclusive rights for developing and marketing Neupro<sup>®</sup> in Japan*
- *Neupro<sup>®</sup> is a dopamine agonist patch that provides continuous drug delivery for patients with Parkinson's disease and Restless Legs Syndrome<sup>2</sup>*
- *Neupro<sup>®</sup> is now available in 35 countries and over 120,000 patients have been treated with Neupro<sup>®</sup> worldwide<sup>3</sup>*

**Brussels (Belgium), December 25 2012** – The Japanese Ministry of Health, Labour and Welfare (MHLW) has approved Neupro<sup>®</sup> (rotigotine transdermal patch) for the treatment of Parkinson's disease (PD) and for the symptomatic treatment of moderate-to-severe idiopathic Restless Legs Syndrome (RLS) in adults.<sup>1</sup> In 2002 Otsuka Pharmaceutical acquired the exclusive rights for developing and marketing Neupro<sup>®</sup> in Japan. UCB is responsible for development and marketing in all other regions worldwide.

Rotigotine is a once-daily transdermal patch which provides continuous delivery of the dopamine agonist over 24 hours.<sup>2</sup> The Japanese approval of rotigotine is supported by randomized, controlled clinical studies in Japanese patients which have demonstrated its efficacy and safety in the treatment of PD and RLS.<sup>3,4,5</sup> These studies have added to the existing data for rotigotine which has led to previous approvals in other regions such as Europe and the US.<sup>2,6</sup> With the Japanese approval rotigotine is approved in 35 countries and over 120,000 patients have been treated with rotigotine worldwide.<sup>7</sup>

"UCB has a long-standing partnership with Otsuka Pharmaceutical and the two companies have successfully co-marketed E-Keppra<sup>®</sup> in the area of epilepsy since 2010. Otsuka Pharmaceutical' leadership and expertise in CNS will provide an excellent platform to introduce rotigotine to Japanese healthcare professionals," said Professor Dr Iris Loew-Friedrich, Chief Medical Officer and Executive Vice President UCB. "Rotigotine will offer healthcare professionals a valuable new treatment option with potential benefits across a



wide range of motor and other underlying symptoms of PD, and in both night- and day-time symptoms of RLS.”

Parkinson’s disease is a chronic, degenerative neurological disease which develops due to the loss of cells in the brain that produce a chemical called dopamine. It is commonly associated with movement (motor) symptoms such as tremors (uncontrollable shaking), rigidity (stiffness or muscle tensing) and bradykinesia (slowness and loss of spontaneous movement), but also commonly causes underlying symptoms such as mood and cognitive changes, pain, depression and fatigue.<sup>8</sup>

Restless Legs Syndrome (RLS) is a neurological disorder characterized by unpleasant sensations in the legs and an uncontrollable urge to move to gain relief.<sup>9</sup> Daytime symptoms of RLS are increasingly recognized.<sup>10</sup> RLS can cause exhaustion and daytime fatigue, and may affect work and personal relationships.<sup>9</sup>

#### **About Neupro<sup>®</sup> in the European Union**

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 occur (end of dose or on-off fluctuations). 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 the European Union 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 to avoid skin burns.

It is recommended to monitor blood pressure, especially at the beginning of treatment, due to the risk of postural/orthostatic hypotension associated with dopaminergic therapy and reported during Neupro<sup>®</sup> treatment. Neupro<sup>®</sup> has been associated with somnolence and episodes of sudden sleep onset. Patients treated with dopamine agonists including Neupro<sup>®</sup>, have been reported 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.

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> 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.

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

In restless legs syndrome augmentation may occur. Augmentation refers to the earlier onset of symptoms in the evening (or even the afternoon), increase in severity of symptoms, and spread of symptoms to involve other body parts.

At the beginning of therapy, dopaminergic adverse reactions, such as nausea and vomiting, may occur. These are usually mild or moderate in intensity and transient, even if treatment is continued.

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. The majority of these application site reactions are mild or moderate in intensity.

Adverse drug reactions reported in more than 10% of RLS patients treated with Neupro<sup>®</sup> are nausea, application site reactions, asthenic conditions (including fatigue, asthenia, malaise) and headache. The majority of these application site reactions are mild or moderate in intensity.

Please refer to the European Summary of Product Characteristics for full prescribing information (Revised September 2012):

[http://www.ema.europa.eu/docs/en\\_GB/document\\_library/EPAR\\_-\\_Product\\_Information/human/000626/WC500026397.pdf](http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Product_Information/human/000626/WC500026397.pdf) [Accessed November 2012]

## References

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#### **About UCB**

UCB, Brussels, Belgium ([www.ucb.com](http://www.ucb.com)) is a global biopharmaceutical company focused on the discovery and development of innovative medicines and solutions to transform the lives of people living with severe diseases of the immune system or of the central nervous system. With more than 8 500 people in about 40 countries, the company generated revenue of EUR 3.2 billion in 2011. UCB is listed on Euronext Brussels (symbol: UCB).

#### **UCB Forward-Looking Statement**

This press release contains forward-looking statements based on current plans, estimates and beliefs of management. All statements, other than statements of historical fact, are statements that could be deemed forward-looking statements, including estimates of revenues, operating margins, capital expenditures, cash, other financial information, expected legal, political, regulatory or clinical results and other such estimates and results. By their nature, such forward-looking statements are not guarantees of future performance and are subject to risks, uncertainties and assumptions which could cause actual results to differ materially 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, the inability to obtain necessary regulatory approvals or to obtain them on acceptable terms, costs associated with research and development, changes in the prospects for products in the pipeline or under development by UCB, effects of future judicial decisions or governmental investigations, product liability claims, challenges to patent protection for products or product candidates, changes in laws or regulations, exchange rate fluctuations, changes or uncertainties in tax laws or the administration of such laws and hiring and retention of its employees. UCB is providing this information as of the date of this press release and expressly disclaims any duty to update any information contained in this press release, either to confirm the actual results or to report a change in its expectations.

There is no guarantee that new product candidates in the pipeline will progress to product approval or that new indications for existing products will be developed and approved. Products or potential products which are the subject of partnerships, joint ventures or licensing collaborations may be subject to differences between the partners. Also, UCB or others could discover safety, side effects or manufacturing problems with its products after they are marketed.

Moreover, sales may be impacted by international and domestic trends toward managed care and health care cost containment and the reimbursement policies imposed by third-party payers as well as legislation affecting biopharmaceutical pricing and reimbursement.