UCB Receives Complete Response Letter from U.S. FDA Regarding Neupro® (*Rotigotine*)

- *FDA recommends reformulation of Neupro® in the U.S.*
- *In Europe and other countries, Neupro® is not impacted by this recommendation*
- *UCB has already made progress in reformulation and remains committed to bringing Neupro® to U.S. patients suffering from Parkinson's disease and Restless Leg Syndrome*

Brussels (Belgium) – April 23, 2010 – regulated information – UCB announced today that the U.S. Food and Drug Administration (FDA) has provided a complete response letter recommending reformulation of Neupro® (*Rotigotine Transdermal System*) before making it available in the U.S. market for the treatment of Parkinson's disease (PD) and restless legs syndrome (RLS). FDA's response is to an NDA Supplement that UCB submitted in June 2009, with a proposal for new refrigerated storage conditions to alleviate crystallization on the patches.

"FDA agrees that the proposed new refrigeration conditions significantly inhibit the degree of crystallization on the patches, but has recommended that the definitive resolution of the crystallization is to reformulate the drug product," said Prof. Dr. Iris Loew-Friedrich, Executive Vice President and Chief Medical Officer of UCB. "This FDA decision does not impact product supply and availability in Europe and the rest of the world. It does not change previous assessments made by the European and other international authorities regarding the cold chain storage process."

More than 50 000 patients are being treated by Neupro® in Europe. In the U.S., a Patient Access Program is ongoing and UCB will continue this program.

"We have already been working on a room-temperature stable, improved formulation of Neupro® and have made significant progress in this area," the Chief Medical Officer of UCB added. "Neupro® has made a meaningful difference for many people with Parkinson's disease and Restless Legs Syndrome. We are committed to obtaining FDA approval so that people in the U.S. who live with these diseases can benefit from Neupro."

About Neupro® in Europe

Neupro® (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® is also approved in the European Union for the symptomatic treatment of moderate to severe idiopathic restless legs syndrome in adults.

Neupro® in Europe Important Safety Information

Neupro® 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® 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® has been associated with somnolence episodes of sudden sleep onset episodes. Patients treated with dopamine agonists including Neupro®, 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® 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® is observed, Neupro® 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®.

Neupro® 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® are nausea, vomiting, application site reactions, somnolence, dizziness and headache.

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

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.

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

Further information

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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 9 000 people in over 40 countries, UCB generated 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.