New post-hoc analyses showed Neupro® (rotigotine) improved common non-motor symptoms in patients with Parkinson’s disease

- Post-hoc analysis of 5 placebo-controlled studies suggested that neuropsychiatric features and fatigue in PD may be improved with transdermal rotigotine

- Post hoc analysis of RECOVER™ study data showed that, in some patients with pain, improvements were observed with transdermal rotigotine

Slough, UK, April 26th 2012, 1800 CET: UCB today announced findings from post-hoc analyses suggesting that treatment with Neupro® (rotigotine) improved common non-motor symptoms in patients with Parkinson’s disease. These data were presented at the 64th American Academy of Neurology Annual Meeting in New Orleans, USA.

Non-motor symptoms (NMS) such as sleep disturbance, mood disorders, gastro-intestinal problems and pain are a major cause of disability for people with Parkinson’s and their carers. More than 90% of people with Parkinson’s experience NMS which can go unreported to healthcare professionals, because people are either embarrassed or unaware that the symptoms are linked to Parkinson's disease. However, in many cases NMS are treatable.

Post-hoc analysis of five placebo-controlled studies of rotigotine transdermal system in patients with early-PD (SP512, SP513), advanced-PD (PREFER, CLEOPATRA-PD), and PD with unsatisfactory control of early-morning motor symptoms (RECOVER) was conducted. Improvements were observed with rotigotine transdermal system versus placebo in items assessing apathy (p<0.04), anhedonia (p=0.026), anxiety (p=0.002), anxiety/depression (p<0.03), depression (p<0.02) and fatigue (p<0.003).

In addition, a post hoc analysis of data from the RECOVER study investigated the effect of rotigotine transdermal system on pain in patients with PD. Patients rated their pain using a Likert pain scale, from 0 (no pain) to 10 (worst pain ever experienced); and the nocturnal akinesia, dystonia and cramps score (NADCS), from 0 (normal) to 4 (maximal severity).

In patients with a pain score ≥1, improvements were observed with rotigotine versus placebo in Likert pain scale change from baseline among patients with a score ≥1 at baseline with a treatment difference of -0.88 (p=0.0128), and in those with a score ≥4 with a treatment difference of -1.38 (p=0.0117). Treatment difference in the 1-3 sub-group was -0.37 (p=0.3756).

In patients with a pain score ≥1, improvements were observed with rotigotine transdermal system versus placebo in NADCS with a treatment difference of -0.54 (p=0.0275). Treatment differences for 1-3 and ≥4 subgroups were -0.47 (p=0.1416), and -0.62 (p=0.0825).

Parkinson’s disease is a progressive, chronic neurodegenerative disease and on average one person in every 500 is affected by Parkinson's disease; that’s about 127,000 people in the UK. It is predominantly characterised by problems with body movements, known as ‘motor symptoms’ – the most recognisable being tremor. However, the NMS are missed by neurologists in approximately 50% of consultations. This is of particular concern as some, but not all, NMS of Parkinson’s are treatable.
Adverse drug reactions reported in more than 10% of Parkinson’s patients treated with rotigotine are nausea, vomiting, application site reactions, somnolence, dizziness and headache. The majority of these application site reactions are mild or moderate in intensity.

For further Information:
Scott Fleming, Head of UK Communications
T +44 770.277.7378, scott.fleming@ucb.com

About Neupro®
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 occur (end of dose or on-off fluctuations). Neupro® is also approved in the European Union for the symptomatic treatment of moderate to severe idiopathic Restless Legs Syndrome in adults.

Neupro® in the European Union 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 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® treatment. Neupro® has been associated with somnolence and episodes of sudden sleep onset. Patients treated with dopamine agonists including Neupro®, 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® 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® 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® 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® 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® 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.

All Neupro® supply should be stored in a refrigerator (2°C-8°C). There is no need for patients to transport Neupro® patches in special containers and they must not be stored in a freezer compartment.

About UCB
UCB, Brussels, Belgium (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 8,000 people in about 40 countries, the company generated revenue of EUR 3.2 billion in 2011. UCB is listed on Euronext Brussels (symbol: UCB).

Forward looking statements: UCB
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.

References