UCB’s new refrigeration-free Neupro® (rotigotine transdermal patch) provides patients with Parkinson’s travel flexibility in time for holiday season

- UCB’s refrigeration-free formulation of Neupro® is now available in UK and Ireland
- Easier to store room temperature formulation to replace existing cold chain formulation

**Slough, 16 August 2013** – The new formulation of Neupro® (rotigotine transdermal patch) that can be stored at room temperature (up to 25°C) is now available to patients in the UK and Ireland. This formulation replaces the existing cold chain formulation of rotigotine.

In the EU, rotigotine (2,4,6 and 8 mg/24 hours) is approved for the treatment of the signs and symptoms of early-stage idiopathic Parkinson’s disease as monotherapy (without levodopa) or in combination with levodopa, i.e. over the course of the disease through to the late stages. Rotigotine (1,2 and 3 mg/24 hours) is also indicated for the symptomatic treatment of moderate-to-severe idiopathic Restless Legs Syndrome in adults (RLS).¹

Parkinson’s disease specialist nurse, Louise Ebenezer said of the rotigotine room temperature patch “many of my patients who travel both in this country and abroad are concerned about the storage of their patches. However with the introduction of the room temperature patch, storage is more convenient and therefore one less thing for patients to worry about.”

As well as being easier to store, the new formulation has a longer shelf life, which will also simplify storage requirements for healthcare providers who dispense the medicine to patients. From now on UCB will only supply the new room temperature formulation, which has a distinctive outer packaging to help prescribers and patients to differentiate between the new room temperature formulation and the existing cold chain formulation that requires refrigeration.

UCB is ensuring that all physicians, pharmacists and patient advocacy groups are informed of this change in formulation of rotigotine patches, so that patients can be advised to check the outer packaging of their rotigotine patches for appropriate storage conditions. A patient information leaflet is available to all patients and can be obtained from their prescriber in order to help manage the transition period from rotigotine patches that require refrigeration, to the new formulation that should be stored at room temperature.
Notes to Editors

About Parkinson’s disease

Parkinson’s disease (PD) is a chronic, degenerative neurological disease which affects approximately seven million to 10 million people worldwide. PD develops with the loss of nerve cells in the brain that produce a chemical called dopamine. The symptoms of PD can have an impact on many dimensions of patients’ lives. As dopamine levels fall, movement (motor) symptoms—tremors (uncontrollable shaking), rigidity (stiffness or muscle tensing) and bradykinesia (slowness and loss of spontaneous movement)—can progress, along with the underlying symptoms of PD, which are less well recognized and may be under-treated. Underlying symptoms occur in over 90% of PD patients and include sleep disturbance, such as insomnia, vivid dreams and daytime drowsiness, mood and cognitive changes, pain, depression, anxiety, apathy, gastrointestinal disorders, sexual dysfunction, bladder problems and fatigue.

About Restless Legs Syndrome

Restless Legs Syndrome (RLS) is a neurological disorder characterized by unpleasant sensations in the legs and an uncontrollable urge to move to gain relief. Over 80% of people with RLS also have periodic limb movement disorder (PLMD), which causes rhythmic limb movements during sleep. RLS affects between three percent and 10 percent of the U.S. population to some extent. Some estimates are much higher because RLS is thought to be underdiagnosed, and in some cases, misdiagnosed. Most people with RLS have difficulty falling asleep and staying asleep. Daytime symptoms of RLS, such as inability to sit still and involuntary leg jerks, are increasingly recognized. While the underlying pathophysiology of RLS is not fully understood, it is thought to involve central dopamine systems. Recent neuroimaging data suggest that RLS patients may carry an abnormality in dopamine transport that can be visualized both day and night. RLS can cause exhaustion and daytime fatigue, and may affect work and personal relationships. Patients with moderate-to-severe RLS are often unable to concentrate, have impaired memory, or fail to accomplish daily tasks. These patients may require long-term treatment for their RLS symptoms.

About Neupro® in the European Union

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.

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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.

References
7. Sethi KD. Restless legs syndrome sees the lights of day. Lancet Neurology 2008 Jul;7(7):564-5
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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
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
depicted 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
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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.