Press Release – Regulated Information

Neupro® recommended for approval in Europe for Restless Legs Syndrome

Brussels, Belgium, 25 April, 2008 at 8:00 am CET – UCB today announced that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMEA) has issued a positive opinion recommending that the European Commission grants a marketing authorisation for Neupro® (rotigotine transdermal patch) in the symptomatic treatment of moderate-to-severe idiopathic Restless Legs Syndrome (RLS) in adults.

The CHMP decision is based on data from two well-controlled clinical trials that evaluated the efficacy and safety of Neupro® over a six month period in almost 1,000 patients with RLS. In these trials, Neupro® showed significant and clinically relevant improvements in RLS symptoms compared to placebo and was generally well tolerated.

"The CHMP recommendation is encouraging news and we are hopeful that the European Commission will act favourably on the marketing authorization for Restless legs syndrome. We will be filing a Restless legs syndrome manufacturing variation with the EMEA. We are looking forward to making Neupro® available as a new therapeutic option to people living with this chronic neurological disorder", said Troy Cox, President CNS Operations, UCB.

Restless Legs Syndrome affects between 3 and 10% of the population, causing unpleasant sensations such as tingling, burning, tugging, gnawing and pulling in the legs. Symptoms frequently occur during periods of rest and inactivity such as during long flights and car trips, or at night.

"Restless Legs Syndrome can have a significant impact on the everyday lives of patients, disrupting their working and leisure activities and disturbing their rest and sleep", said Professor Claudia Trenkwalder, Paracelsus-Elena Klinik, Kassel and University of Goettingen, Germany. "In clinical trials, over a six month period, rotigotine provided clinical improvement to patients negatively impacted by the symptoms of Restless Legs Syndrome. A further new treatment would be a welcome option for patients and physicians."

Neupro® is approved in Europe for the treatment of the signs and symptoms of early-stage idiopathic Parkinson's disease as monotherapy and as adjunctive therapy with levodopa for advanced-stage Parkinson's disease.

Key study results

The data supporting the licence application is based on the results of two fixed-dose, randomized, double-blind, placebo-controlled efficacy and safety studies that evaluated rotigotine for the treatment of moderate-to-severe idiopathic RLS in almost 1 000 patients from EU and US over six months.

The efficacy of rotigotine (0.5-3 mg/ 24 hours) was evaluated by using the International Restless Legs Severity Scale (IRLS), a clinician-administered tool considered to be the best scale for evaluating the severity and frequency of RLS symptoms and the degree to which they affect sleep and daily life. Additionally the change in the severity of illness was evaluated by monitoring the Clinical Global Impressions (CGI) Item 1 scores.

In both studies, rotigotine (2 mg/ 24 hours and 3 mg/ 24 hours) was shown to have a statistically significant and clinically relevant improvement in the IRLS sum scores and a reduction in the CGI-1 score compared to placebo, with sustained improvement observed throughout the six-month maintenance phase.

The most frequently reported adverse events associated with rotigotine in these studies were application site reactions, nausea, dizziness, somnolence and headache.

About Restless Legs Syndrome: Restless legs syndrome (RLS) is a chronic neurological disorder that affects between 3 and 10% of the population to some extent. It is characterized by unpleasant feelings in the legs and an irresistible urge to move in order to relieve the discomfort. RLS sensations are frequently described as tingling, burning, tugging, gnawing and pulling. The exact cause of RLS is not known; however, recent clinical research has linked certain genes to RLS, suggesting that the disorder is genetically based.

Symptoms of RLS typically appear during periods of rest and inactivity, particularly in the evenings and at night. This can make it difficult to fall asleep and stay asleep, thus preventing recuperative sleep and often leading to daytime fatigue and reduced alertness. While RLS symptoms are generally most pronounced in the evening and while at rest, other periods of inactivity, such as long flights, car trips and sitting in a theatre or cinema, can also trigger symptoms.

About Neupro® in Europe: In Europe, Neupro® is indicated for the treatment of the signs and symptoms of early-stage idiopathic Parkinson's disease as monotherapy and in combination with levodopa for advanced stage Parkinson's disease.

Important Safety Information

Neupro® has been associated with somnolence and episodes of sudden sleep onset, particularly in patients with Parkinson's disease. Sudden onset of sleep during daily activities in some cases without awareness of any warning signs, has been reported. Pathologic gambling, increased libido and hypersexuality have been reported in patients treated with dopamine agonists for Parkinson's disease, including Neupro®.

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.

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

Caution is advised when treating patients with severe hepatic impairment which may result in lower rotigotine clearance.

Adverse drug reactions reported in more than 10% of patients treated with Neupro® transdermal patch are nausea, dizziness, somnolence and application site reactions. Application site reactions are usually mild or moderate in intensity and it is recommended that the application site should be rotated on a daily basis.

Neupro® is a registered trademark and is distributed by Schwarz Pharma, a company of UCB Group.

About UCB

UCB (Brussels, Belgium) (www.ucb-group.com) is a global leader in the biopharmaceutical industry dedicated to the research, development and commercialization of innovative pharmaceutical and biotechnology products in the fields of central nervous system disorders, allergy/respiratory diseases, immune and inflammatory disorders and oncology. UCB focuses on securing a leading position in severe disease categories. Employing around 12 000 people in over 40 countries, UCB achieved revenue of 3.6 billion euro in 2007. UCB S.A. is listed on Euronext Brussels.

Further information

Antje Witte, Vice-President Corporate Communications & Investor Relations, UCB Group
T +32.2.559.9414, Antje.witte@ucb-group.com

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.