UCB News

UCB announces first presentation of data from NEUPRO® (rotigotine transdermal patch) Phase 3 study in China at international congress

- Data from study in patients with early-stage Parkinson's disease presented at the 19th International Congress of Parkinson's Disease and Movement Disorders

Brussels (Belgium), 16 June – 0700 (CET) – UCB announced today efficacy and safety data from a Phase 3 study evaluating NEUPRO® (rotigotine transdermal patch) in the treatment of patients in China with early-stage Parkinson's disease (PD).[1] Results showed that rotigotine significantly improved activities of daily living and motor function compared with placebo. The adverse event profile observed in this population was consistent with that known for rotigotine.[2] The data were presented this week at the 19th International Congress of Parkinson's Disease and Movement Disorders (MDS) in San Diego, June 14-18, 2015.

"In this Phase 3 study, transdermally delivered rotigotine resulted in significant benefits in control of activities of daily living as well as motor symptoms in patients with early-stage Parkinson's disease and also resulted in a greater number of responders compared with placebo. The adverse event profile was similar to that seen in rotigotine studies in the previously studied Caucasian population." said Professor Zhang, MD, from Peking Union Medical College Hospital, Beijing, China.

This Phase 3, multicenter, randomized, double-blind, placebo-controlled study conducted in China, was designed to evaluate the efficacy and safety of rotigotine (2-8 mg/24 hours) in 247 adult patients (mean age of 59.4 years ± 10.2 SD) with early-stage idiopathic PD over 24 weeks of treatment after patients reached their optimal dose. The primary efficacy variable was the change over the course of treatment in the total score of the activities of daily living (ADL) section and motor examination section of the Unified Parkinson's Disease Rating Scale (UPDRS). Secondary variables included patients' response to therapy defined as 20% or more improvement in the UPDRS ADL and motor examination sections total score (20% responder rates).[1]

Efficacy Results[1]

- Rotigotine significantly improved the UPDRS ADL and motor examination total score compared with placebo ($p<0.0001$). The mean (±SD) change from baseline was -4.9 (±9.9) for rotigotine (n=123) vs. -0.2 (±9.9) for placebo (n=121).
- Both the individual ADL and motor examination subscores also improved with rotigotine compared with placebo ($p<0.0001$, and $p=0.0004$, respectively).
- The 20% responder rates were higher with rotigotine vs. placebo (42.3% vs. 22.3%).

Safety/Tolerability Results[1]

- The most commonly reported adverse events for the rotigotine (n=124) and placebo (n=123) groups were nausea (8.9% rotigotine vs. 3.3% placebo), dizziness (8.1% vs. 5.7%), pruritus (8.1% vs. 4.1%), somnolence (8.1% vs. 3.3%), erythema (6.5% vs. 1.6%), and vomiting (5.6% vs. 1.6%).
- Overall, 5.3% patients discontinued due to adverse events (4.8% rotigotine vs. 5.7% placebo).

NEUPRO is currently available as a treatment for Parkinson's disease in over 46 countries worldwide, including the US, the European Union and Japan. NEUPRO is not approved in China for the treatment of Parkinson's disease. UCB plans to submit a regulatory application in China in 2015 for NEUPRO in Parkinson's disease.

About Parkinson's Disease[3]

Parkinson's disease is a progressive and chronic neurological disease characterized by the physical motor symptoms of resting tremor, muscle rigidity and slowness of movement. Symptoms not related to movement (non-motor symptoms) can also occur and include pain, sleep disturbances and depression. It is estimated that 6.3 million people are living with Parkinson's disease worldwide. The age of onset is usually over 60 years. Although it is estimated that 1 in 10 people are diagnosed before the age of 50.

About NEUPRO in the European Union[2]

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[2]

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 ofpostural/orthostatic hypotension associated with dopaminergic therapy and reported during NEUPOR treatment. NEUPRO has been associated with somnolence and episodes of sudden sleep onset. Patients treated with dopamine agonists, including NEUPRO, have been reported to exhibit behavioural symptoms of impulse control disorders such as pathologic gambling, increased libido, hypersexuality, compulsive spending or buying, binge eating and compulsive eating. Symptoms suggestive of neuroleptic malignant syndrome have been reported with abrupt withdrawal of dopaminergic therapy. Therefore it is recommended to taper treatment.

Patients should be informed that manifestations of abnormal thinking and behaviour such as paranoid ideation, delusions, hallucinations, confusion, psychotic-like behaviour, disorientation, aggressive behaviour, agitation and delirium 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. Exposure of a skin rash or irritation to direct sunlight could lead to changes in the skin colour. Application site reactions lasting more than a few days, spreading outside the area of the patch, or that increase in severity should lead to risk/benefit balance re-assessment. If a generalised skin reaction (eg, 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.

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 Parkinson's disease, 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.

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 the 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 the application site reactions are mild or moderate in intensity.

Please refer to the European Summary of Product Characteristics for full prescribing information http://www.ema.europa.eu/ema/ (Date of final CHMP opinion of the EU Product Information: 26 February 2015)

NEUPRO is a registered trademark of the UCB Group of Companies.

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References

1. Zhang Z *et al.* Efficacy and safety of rotigotine transdermal patch in Chinese patients with early-stage Parkinson's disease: a randomized, double-blind, placebo-controlled study. Presented at the 19th International Congress of Parkinson's Disease and Movement Disorders, San Diego, U.S. June 14-18, 2015.

2. NEUPRO® Summary of Product Characteristics. Accessed 1st April 2015 from http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Product_Information/human/000626/WC500026397.pdf

3. European Parkinson's Disease Association. Accessed 1st April 2015 from http://www.epda.eu.com/en/parkinsons/in-depth/parkinsonsdisease

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 8500 people in approximately 40 countries, the company generated revenue of € 3.3 billion in 2014. UCB is listed on Euronext Brussels (symbol: UCB). Follow us on Twitter: @UCB_news

Forward looking statements

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.