



## Important UCB presence at the 2015 American Academy of Neurology Meeting

**Brussels, April 20, 2015 – 7:00 a.m. (EDT)** – UCB, a global biopharmaceutical company focusing on neurology and immunology treatment and research, is sponsoring a total of 24 data presentations at the 67<sup>th</sup> Annual Meeting of the American Academy of Neurology (AAN) in Washington, DC, April 18-25, 2015. Many of the presentations include new data on VIMPAT<sup>®</sup> (lacosamide) C-V and NEUPRO<sup>®</sup> (rotigotine).

“We are pleased to continue sharing data that deepens our understanding of the clinical utility of UCB’s treatments in a wide range of patients with neurological disorders,” said Professor Dr. Iris Loew Friedrich, Chief Medical Officer and Executive Vice President, UCB. “We support studies across our portfolio of medicines that help physicians make the most appropriate treatment decisions for their patients – reflecting our long-held commitment to providing patient-centric health solutions.”

In the U.S., VIMPAT is indicated in patients 17 years and older with partial-onset seizures as monotherapy or adjunctive therapy. VIMPAT injection for intravenous use is an alternative when oral administration is temporarily not feasible. In the European Union, VIMPAT is indicated as adjunctive therapy for the treatment of partial-onset seizures with or without secondary generalization in adult and adolescent (16-18 years) patients with epilepsy.<sup>1,2</sup>

In the U.S., NEUPRO is indicated for the treatment of Parkinson’s disease and moderate-to-severe primary Restless Legs Syndrome (RLS). In the European Union, NEUPRO is indicated 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), and for the symptomatic treatment of moderate-to-severe idiopathic RLS in adults.<sup>3,4</sup>

### UCB-Sponsored Posters on VIMPAT (lacosamide) at AAN

- High Predictability of Plasma Lacosamide and No Relevant Differences by Age and Gender Following Normalization
  - Date/Time: Wednesday, April 22, 7:30 AM-12:00 PM
  - Session: Poster Session IV: Epilepsy/Clinical Neurophysiology (EEG): Pharmaceuticals II
  - Poster Number: P4.261
- Immediate Steady-state Concentrations in Plasma after Oral or Intravenous Lacosamide Loading Dose
  - Date/Time: Wednesday, April 22, 7:30 AM-12:00 PM

- Session: Poster Session IV: Epilepsy/Clinical Neurophysiology (EEG):  
Pharmaceuticals II
  - Poster Number: P4.263
  
- Safety and tolerability of lacosamide monotherapy in elderly: a subgroup analysis from pooled lacosamide trials
  - Date/Time: Monday, April 20, 2:00 PM-6:30 PM
  - Session: Poster Session I: Epilepsy/Clinical Neurophysiology (EEG):  
Pharmaceuticals I
  - Poster Number: P1.239
  
- Conversion to Lacosamide Monotherapy: Post-hoc Analysis on Responder and Seizure Freedom Rates by Patients' Baseline Characteristics
  - Date/Time: Wednesday, April 22, 7:30 AM-12:00 PM
  - Session: Poster Session IV: Epilepsy/Clinical Neurophysiology (EEG):  
Pharmaceuticals II
  - Poster Number: P4.260
  
- Responder Rates by Study Phase in Conversion to Lacosamide Monotherapy Study: a Post-hoc Analysis
  - Date/Time: Thursday, April 23, 2:00 PM-6:30 PM
  - Session: Poster Session VII: Epilepsy/Clinical Neurophysiology (EEG) Poster  
Discussion Session
  - Poster Number: P7.007
  
- Safety and Effectiveness of Lacosamide as a First Add-on (FAO) or Later Add-on (LAO) Treatment of Partial-onset Seizures (POS) in Adults: an Open-label Trial
  - Date/Time: Wednesday, April 22, 7:30 AM-12:00 PM
  - Session: Poster Session IV: Epilepsy/Clinical Neurophysiology (EEG):  
Pharmaceuticals II
  - Poster Number: P4.262
  
- Safety and Effectiveness of Lacosamide as Adjunctive Treatment for Partial-onset Seizures (POS) in Hispanic/Latino Patients from Mexico: Post-hoc Analysis of an Open-label Trial
  - Date/Time: Wednesday, April 22, 7:30 AM-12:00 PM
  - Session: Poster Session IV: Epilepsy/Clinical Neurophysiology (EEG):  
Pharmaceuticals II
  - Poster Number: P4.265
  
- Cross-titration of lacosamide with a Sodium Channel Blocker in Patients with Partial-onset Seizures on a Stable Dose Regimen of Levetiracetam: Safety and Efficacy
  - Date/Time: Monday, April 20, 2:00 PM-6:30 PM
  - Session: Poster Session I: Epilepsy/Clinical Neurophysiology (EEG):  
Pharmaceuticals I

- Poster Number: P1.240
- Comparative Cognitive Effects of Lacosamide versus Carbamazepine
  - Date/Time: Tuesday, April 21, 2:00 PM-6:30 PM
  - Session: Poster Session III: Epilepsy/Clinical Neurophysiology (EEG): Cognition and Behavioral Health
  - Poster Number: P3.191
- Tolerability of Lacosamide 200 mg/day Starting Dose: Post-hoc Analysis of Conversion to Lacosamide Monotherapy Study
  - Date/Time: Wednesday, April 22, 7:30 AM-12:00 PM
  - Session: Poster Session IV: Epilepsy/Clinical Neurophysiology (EEG): Pharmaceuticals II
  - Poster Number: P4.264
- Lacosamide Monotherapy Treatment Pathways in Epilepsy Patients in a US Managed Care Population
  - Date/Time: Tuesday, April 21, 2:00 PM-6:30 PM
  - Session: Poster Session III: Epilepsy/Clinical Neurophysiology (EEG): Health Services
  - Poster Number: P3.201
- Lacosamide Added to a Baseline Monotherapy in Patients with Partial-onset Seizures (POS): Efficacy and Safety Across Center Types in the VITObA Study
  - Date/Time: Wednesday, April 22, 7:30 AM-12:00 PM
  - Session: Poster Session IV: Epilepsy/Clinical Neurophysiology (EEG): Pharmaceuticals II
  - Poster Number: P4.266
- Lacosamide Added to an Existing Monotherapy in Epilepsy Patients with Partial-onset Seizures: A Subgroup Analysis of Elderly Patients in the VITObA Study
  - Date/Time: Wednesday, April 22, 7:30 AM-12:00 PM
  - Session: Poster Session IV: Epilepsy/Clinical Neurophysiology (EEG): Pharmaceuticals II
  - Poster Number: P4.267

### UCB-Sponsored Posters on NEUPRO (rotigotine) at AAN

- 24-hour Efficacy Profile of Rotigotine in Patients with Advanced Parkinson's Disease: A Post-hoc Analysis
  - Date/Time: Thursday, April 23, 7:30 AM-12:00 PM
  - Session: Poster Session VI: Movement Disorders: Parkinson's Disease
  - Poster Number: P6.057
- First 1-year Real-life Study to Assess Management of Augmentation of Restless Legs Syndrome by Switching to Rotigotine Transdermal System

- Date/Time: Thursday, April 23, 2:00 PM-6:30 PM
- Session: Poster Session VII: Sleep: Restless Legs and REM Disorders
- Poster Number: P7.304
  
- Incidence of Impulsive and Compulsive Behavior Type Adverse Events with Long-term Rotigotine: A Post-hoc Analysis
  - Date/Time: Sunday, April 19, 11:35 AM-12:00 PM
  - INS poster session: Dopamine-mediated Neural Plasticity in Motor and Non-motor Circuits Poster Presentations
  - Poster Number: I3-5E
  
- Rotigotine in Combination with the MAO-B Inhibitor Selegiline in Early Parkinson's disease: A Post-hoc Analysis
  - Date/Time: Tuesday, April 21, 2:00 PM-6:30 PM
  - Session: P3: Poster Session III: Movement Disorders: Myoclonus, Paroxysmal Dyskinesias, and Parkinson's Disease
  - Poster Number: P3.026
  
- Rotigotine in Patients with PD and Unsatisfactory Early-morning Motor Symptom Control: a Post-hoc Analysis of Efficacy and Safety by Dose
  - Date/Time: Monday, April 20, 2:00 PM-6:30 PM
  - Session: Poster Session I: Movement Disorders: Parkinson's Disease Pharmacotherapy
  - Poster Number: P1.190
  
- Rotigotine in Patients with Restless Legs Syndrome and End-stage Renal Disease Requiring Hemodialysis
  - Date/Time: Thursday, April 23, 2:00 PM-6:30 PM
  - Session: Poster Session VII: Movement Disorders: Restless Legs Syndrome
  - Poster Number: P7.298

### UCB-Sponsored Posters on Parkinson's Disease at AAN

- The Incidence of Falls and Fractures in Patients with Parkinson's Disease in a US Population
  - Session: Poster Session VI: Movement Disorders: Parkinson's Disease
  - Date/Time: Thursday, April 23, 7:30 AM-12:00 PM
  - Poster Number: P6.055

### About Epilepsy<sup>5,6,7</sup>

Epilepsy is a chronic neurological disorder affecting approximately 65 million people worldwide and more than 2 million people in the U.S. It is the fourth most common neurological disorder in the U.S. Anyone can develop epilepsy; it occurs across all ages, races and genders and is considered to be a disease of the brain defined by any of the following conditions: (1) at least two unprovoked (or reflex) seizures occurring >24 hours apart; (2) one unprovoked (or reflex) seizure and a probability of further seizures similar to the general recurrence risk (at least 60%) after two unprovoked seizures,

occurring over the next 10 years; (3) diagnosis of an epilepsy syndrome. Antiepileptic drug monotherapy is in general the initial management approach in epilepsy care, since many patients may be successfully managed with the first or second monotherapy utilized.

### About VIMPAT<sup>1</sup>

VIMPAT is approved in the U.S. as tablets, injection and oral solution as monotherapy or adjunctive therapy in the treatment of partial-onset seizures in people with epilepsy ages 17 years and older. VIMPAT injection is a short-term replacement when oral administration is not feasible in these patients. The availability of the oral tablets, oral solution, and intravenous (IV) injection formulations permits flexibility in administration.

A single 200mg loading dose administration option is also approved in the U.S. for all formulations of VIMPAT when used as monotherapy or adjunctive therapy in the treatment of partial-onset seizures in patients with epilepsy aged 17 years and older.

Since the initial launch of VIMPAT tablets and injection in May 2009, there have been more than 200,000\* VIMPAT patient exposures in the U.S.

In the European Union, VIMPAT (film-coated tablets, syrup and solution for infusion) is approved as adjunctive therapy for the treatment of partial-onset seizures with or without secondary generalization in adult and adolescent (16-18 years) patients with epilepsy. VIMPAT is also approved in the European Union for initiation as a single loading dose of 200 mg, followed approximately 12 hours later by a 100 mg twice-daily maintenance dose regimen.

Important safety information about VIMPAT in the U.S. and the European Union is available below.

### **IMPORTANT SAFETY INFORMATION ABOUT VIMPAT IN THE U.S.**<sup>1</sup>

#### Warnings and Precautions

- **Suicidal Behavior and Ideation:** Antiepileptic drugs (AEDs), including VIMPAT, increase the risk of suicidal behavior and ideation. Monitor patients taking VIMPAT for the emergence or worsening of depression, suicidal thoughts or behavior, and/or any unusual changes in mood or behavior. Advise patients and caregivers to be alert for these behavioral changes and to immediately report them to the healthcare provider.
- **Dizziness and Ataxia:** VIMPAT may cause dizziness and ataxia. The onset of dizziness and ataxia was most commonly observed during titration. Accordingly, patients should be advised not to drive, operate complex machinery, or engage in other hazardous activities until they are familiar with the effects of VIMPAT on their ability to perform such activities.
- **Cardiac Rhythm and Conduction Abnormalities:**  
PR interval prolongation

Dose-dependent prolongations in PR interval with VIMPAT have been observed in clinical studies in patients and in healthy volunteers. Second degree and complete AV block have been reported in patients in pain studies and in patients with seizures. When VIMPAT is given with other drugs that prolong the PR interval, further PR prolongation is possible.

VIMPAT should be used with caution in patients with known cardiac conduction problems (e.g., marked first-degree AV block, second-degree or higher AV block and sick sinus syndrome without pacemaker), sodium channelopathies (e.g., Brugada Syndrome), or with severe cardiac disease such as myocardial ischemia or heart failure, or structural heart disease. VIMPAT should also be used with caution in patients on concomitant medications that prolong PR interval (e.g., beta-blockers and calcium channel blockers) because of a risk of AV block or bradycardia. In such patients, obtaining an ECG before beginning VIMPAT, and after VIMPAT is titrated to steady-state, is recommended. In addition, these patients should be closely monitored if they are administered VIMPAT through the intravenous route.

#### Atrial fibrillation and Atrial flutter

VIMPAT administration may predispose to atrial arrhythmias (atrial fibrillation or flutter), especially in patients with diabetic neuropathy and/or cardiovascular disease.

- Syncope: VIMPAT may cause syncope.
- Withdrawal of Antiepileptic Drugs: VIMPAT should be gradually withdrawn (over a minimum of 1 week) to minimize the potential of increased seizure frequency.
- Multiorgan Hypersensitivity Reactions: Multiorgan hypersensitivity reactions (also known as Drug Reaction with Eosinophilia and Systemic Symptoms, or DRESS) have been reported with antiepileptic drugs. If this reaction is suspected, VIMPAT should be discontinued and alternative treatment started.
- Phenylketonurics: VIMPAT oral solution contains aspartame, a source of phenylalanine. A 200 mg dose of VIMPAT oral solution (equivalent to 20 mL) contains 0.32 mg of phenylalanine.

#### Adverse Reactions

- Adjunctive therapy: In the placebo controlled clinical trials, the most frequently seen adverse reaction with VIMPAT was dizziness (31% vs 8% placebo). Other common adverse reactions occurring in  $\geq 10$  percent of VIMPAT-treated patients, and greater than placebo, were headache, nausea, and diplopia.
- Monotherapy: In the clinical trial, adverse reactions were generally similar to those observed and attributed to drug in adjunctive placebo controlled trials, with the exception of insomnia (observed at a higher rate of  $\geq 2\%$ ).
- Injection: In adjunctive therapy clinical trials, adverse reactions with intravenous administration generally were similar to those observed with the oral formulation, although intravenous administration was associated with local adverse events such as injection site



pain or discomfort (2.5%), irritation (1%), and erythema (0.5%). When administering a loading dose, the incidence of CNS adverse reactions, such as dizziness, somnolence, and paresthesia may be higher with 15-minute administration than over a 30-to 60-minute period.

### Dosing Considerations

The loading dose should be administered with medical supervision considering the VIMPAT pharmacokinetics and increased incidence of CNS adverse reactions. Dosage adjustments are recommended for patients with mild or moderate hepatic impairment or severe renal impairment. Use in patients with severe hepatic impairment is not recommended. Dose titration should be performed with caution in all patients with renal and/or hepatic impairment.

VIMPAT is a Schedule V controlled substance.

Please refer to full Prescribing Information provided by the sales representative and visit [vimpat.com/hcp](http://vimpat.com/hcp).

For more information on VIMPAT® contact 844-599-CARE (2273).

VIMPAT® is a registered trademark used under license from Harris FRC Corporation.

### **Important Safety Information about VIMPAT in the EU and EEA<sup>2</sup>**

VIMPAT (lacosamide) is indicated as adjunctive therapy in the treatment of partial-onset seizures with or without secondary generalization in adult and adolescent (16-18 years) patients with epilepsy. VIMPAT therapy can be initiated with either oral or IV administration. A single loading dose may be initiated in patients in situations when the physician determines that rapid attainment of lacosamide steady state plasma concentration and therapeutic effect is warranted. It should be administered under medical supervision with consideration of the potential for increased incidence of CNS adverse reactions. Administration of a loading dose has not been studied in acute conditions such as status epilepticus. Contraindications: Hypersensitivity to the active substance or any of the excipients; known second- or third-degree atrioventricular (AV) block. Special warnings and precautions for use: Treatment with VIMPAT has been associated with dizziness which could increase the occurrence of accidental injury or falls. Therefore, patients should be advised to exercise caution until they are familiar with the potential effects of the medicine. Prolongations in PR interval with VIMPAT have been observed in clinical studies. Cases with second- and third-degree AV block associated with VIMPAT treatment have been reported in post-marketing experience. VIMPAT should be used with caution in patients with known conduction problems or severe cardiac disease such as a history of myocardial infarction or heart failure. Caution should especially be exerted when treating elderly patients as they may be at an increased risk of cardiac disorders or when VIMPAT is used in combination with products known to be associated with PR prolongation. In the placebo-controlled trials of VIMPAT in epilepsy patients, atrial fibrillation or flutter were not reported; however both have been reported in open-label epilepsy trials and in post-marketing experience. Patients should be

made aware of the symptoms of second-degree or higher AV block (e.g. slow or irregular pulse, feeling of lightheaded and fainting) and of the symptoms of atrial fibrillation and flutter (e.g. palpitations, rapid or irregular pulse, shortness of breath). Patients should be counseled to seek medical advice should any of these symptoms occur. Suicidal ideation and behaviour have been reported in patients treated with antiepileptic agents in several indications. Therefore patients should be monitored for signs of suicidal ideation and behaviours and appropriate treatment should be considered. Patients (and caregivers of patients) should be advised to seek medical advice should signs of suicidal ideation or behaviour emerge. VIMPAT syrup contains sodium methyl parahydroxybenzoate (E219) which may cause allergic reactions (possibly delayed). It contains 3.7 g sorbitol (E420) per dose (200 mg lacosamide), corresponding to a calorific value of 9.7 kcal. Patients with rare hereditary problems of fructose intolerance should not take this medicine. The syrup contains aspartame (E951), a source of phenylalanine, which may be harmful for people with phenylketonuria. VIMPAT syrup and the solution for infusion contain sodium, which should be taken into consideration for patients on a controlled sodium diet. Effects on ability to drive and use machines: VIMPAT may have minor to moderate influence on the ability to drive and use machines. VIMPAT treatment has been associated with dizziness or blurred vision. Accordingly patients should be advised not to drive a car or to operate other potentially hazardous machinery until they are familiar with the effects of VIMPAT on their ability to perform such activities. Undesirable effects: The most common adverse reactions ( $\geq 10\%$ ) are dizziness, headache, diplopia, and nausea. They were usually mild to moderate in intensity. Some were dose-related and could be alleviated by reducing the dose. Incidence and severity of CNS and gastrointestinal (GI) adverse reactions usually decreased over time. Incidence of CNS adverse reactions such as dizziness may be higher after a loading dose. Other common adverse reactions ( $\geq 1\%$  -  $< 10\%$ ) are depression, confusional state, insomnia, balance disorder, coordination abnormal, memory impairment, cognitive disorder, somnolence, tremor, nystagmus, hypoesthesia, dysarthria, disturbance in attention, paraesthesia, vision blurred, vertigo, tinnitus, vomiting, constipation, flatulence, dyspepsia, dry mouth, diarrhoea, pruritus, rash, muscle spasms, gait disturbance, asthenia, fatigue, irritability, feeling drunk, injection site pain or discomfort (local adverse events associated with intravenous administration), irritation (local adverse events associated with intravenous administration), fall, and skin laceration, contusion. The use of VIMPAT is associated with dose-related increase in the PR interval. Adverse reactions associated with PR interval prolongation (e.g. atrioventricular block, syncope, bradycardia) may occur. Laboratory abnormalities: Abnormalities in liver function tests have been observed in controlled trials with VIMPAT in adult patients with partial-onset seizures who were taking 1-3 concomitant antiepileptic drugs. Elevations of ALT to  $\geq 3 \times \text{ULN}$  occurred in 0.7% (7/935) of VIMPAT patients and 0% (0/356) of placebo patients. Multiorgan Hypersensitivity Reactions: Multiorgan hypersensitivity reactions (also known as Drug Reaction with Eosinophilia and Systemic Symptoms, DRESS) have been reported in patients treated with some antiepileptic agents. These reactions are variable in expression but typically present with fever and rash and can be associated with involvement of different organ systems. If multiorgan hypersensitivity reaction is suspected, VIMPAT should be discontinued.



Refer to the European Summary of Product Characteristics for other adverse reactions and full prescribing information. Date of revision: 23 October 2014.

<http://www.ema.europa.eu/ema>

*\* This information is an estimate derived from the use of information under license from the following IMS Health information service - IMS Health Total Patient Tracker - for the period April 2009 through May 2014. IMS expressly reserves all rights, including rights of copying, distribution and republication.*

### **About Parkinson's Disease (PD)<sup>8,9,10</sup>**

Approximately 4-6 million people worldwide and 1 million Americans currently live with PD, a chronic, progressive, neurological disease that occurs when certain cells in the brain stop producing enough of a chemical called dopamine. Dopamine plays several important roles in the body, and a lack of dopamine can cause a wide range of symptoms affecting multiple body systems. The symptoms of PD include both motor and non-motor symptoms. Motor symptoms include shaking or tremor at rest, slowness of movement called bradykinesia, stiffness or rigidity in the arms, legs or trunk and trouble with balance and falls.

### **About Restless Legs Syndrome<sup>11</sup>**

RLS is characterized by unpleasant sensations in the legs and an uncontrollable urge to move to gain relief. Most people with RLS have difficulty falling asleep and staying asleep.

Patients with moderate-to-severe RLS may require long-term treatment for their RLS. While the underlying pathophysiology of RLS is not fully understood, it is thought to involve central dopamine systems.

### **About NEUPRO in the U.S.<sup>3</sup>**

NEUPRO (rotigotine transdermal system) is indicated for the treatment of Parkinson's disease and moderate-to-severe primary Restless Legs Syndrome (RLS). For more information about Neupro visit [www.neupro.com](http://www.neupro.com).

### **NEUPRO in the U.S. Important Safety Information<sup>3</sup>**

NEUPRO contains sodium metabisulfite, a sulfite that may cause allergic-type reactions including anaphylactic symptoms and life-threatening or less severe asthmatic episodes in certain susceptible people and is seen more frequently in people with asthma.

Patients treated with NEUPRO have reported somnolence and falling asleep without warning signs during activities of daily living, including driving, which sometimes resulted in accidents. Some patients believed they were alert immediately prior to the event. Patients may not recognize or acknowledge increased drowsiness or sleepiness. Therefore, prescribers should directly question patients about these possible occurrences and continually reassess patients, as some events have been reported well after the start of treatment. Patients should be advised to exercise caution while driving, operating heavy machinery, or working at heights during treatment with NEUPRO. If patients develop daytime sleepiness or episodes of falling asleep during activities of daily living, NEUPRO should be discontinued.

There is an increased risk for hallucinations in patients with advanced-stage Parkinson's disease treated with NEUPRO. Patients also may experience new or worsening mental status and behavioral

changes, which may be severe, including psychotic behavior during NEUPRO treatment or after starting or increasing the dose of NEUPRO.

NEUPRO may cause symptomatic postural/orthostatic hypotension, and Parkinson's disease patients appear to have an impaired capacity to respond to postural challenge. Both Parkinson's disease and Restless Legs Syndrome patients treated with dopamine agonists require careful monitoring for signs and symptoms of postural hypotension, especially during dose escalation, and should be informed of this risk. NEUPRO may also cause syncope, elevated blood pressure, elevated heart rate, weight gain, and fluid retention. These events should be considered when treating patients with cardiovascular disease or concomitant illnesses.

Patients may experience intense urges to gamble, increased sexual urges, intense urges to spend money, binge eating, and other intense urges, and the inability to control these urges while taking medications, including NEUPRO, that increase central dopaminergic tone and that are generally used for the treatment of Parkinson's disease. Because patients may not recognize these behaviors as abnormal, prescribers should specifically ask patients and their caregivers about the development of new or increased urges while being treated with NEUPRO. Dose reduction or discontinuation of NEUPRO should be considered if such urges develop.

NEUPRO may increase the dopaminergic side effects of levodopa and may cause or exacerbate pre-existing dyskinesia in patients with Parkinson's disease.

NEUPRO can cause application site reactions, and some may be severe. In clinical trials, most reactions were mild or moderate in intensity and were limited to the patch area. Patients with Parkinson's disease have a higher risk of developing melanoma than the general population. Patients should be monitored for melanomas frequently when using NEUPRO.

Use of dopaminergic medications, including NEUPRO, may cause augmentation and rebound in patients with Restless Legs Syndrome.

NEUPRO should be removed before magnetic resonance imaging or cardioversion, because the aluminum backing layer in the patch could cause skin burns. Heat application has been shown to increase absorption several fold with other transdermal products. Therefore, patients should be advised to avoid exposing the application site to sources of direct heat, such as heating pads or electric blankets, heat lamps, saunas, hot tubs, heated water beds, and prolonged direct sunlight.

The most common adverse reactions (at least 5% greater than placebo) for NEUPRO in the treatment of Parkinson's disease are nausea, vomiting, somnolence, application site reactions, dizziness, anorexia, disturbances in initiating and maintaining sleep, hyperhidrosis, visual disturbance, peripheral edema, and dyskinesia. The most common adverse reactions (at least 5% greater than placebo) for NEUPRO in the treatment of Restless Legs Syndrome are application site reactions, nausea, disturbances in initiating and maintaining sleep, somnolence, and headache.

Additional important safety information for NEUPRO can be accessed at [www.neupro.com/pi](http://www.neupro.com/pi).

### **About Neupro in the European Union<sup>4</sup>**

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<sup>4</sup>**

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 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)

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## References

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#### About UCB

UCB, Brussels, Belgium ([www.ucb.com](http://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- 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.

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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.