UCB News

Multiple data presentations at leading European epilepsy congress highlight UCB's commitment to advancing epilepsy research

- New clinical data to be presented on VIMPAT® (lacosamide) as early adjunctive therapy for partial-onset seizures in adults
- Scientific data to be presented on the investigational pipeline product brivaracetam

Brussels (Belgium), Wednesday 25th June, 2014 – 0700 (CEST) – UCB, a global biopharmaceutical company with a focus on CNS treatment and research, is pleased to sponsor new data from its epilepsy portfolio at the 11th European Congress on Epileptology (ECE) in Stockholm, Sweden (June 29 - July 3, 2014). Clinical data to be presented on VIMPAT® (lacosamide) and scientific data on the investigational medicine brivaracetam underpins the company's long-term commitment to epilepsy and to advancement of research for the future management of the disease.

"The UCB-sponsored data presentations at this year's ECE highlight the latest clinical findings and real world data with VIMPAT®, and recent scientific research with our investigational pipeline product brivaracetam, demonstrating our commitment to addressing the unmet needs of people with epilepsy." said Professor Dr. Iris Loew Friedrich, Chief Medical Officer and Executive Vice President, UCB.

Among the 10 UCB-sponsored presentations at ECE 2014 will be new data evaluating VIMPAT® as early adjunctive therapy in the treatment of patients with partial-onset seizures. Final analysis will also be presented from the VITOBA™ study (**VI**MPAT® added **T**o **O**ne **B**aseline **A**ED) which was designed to evaluate lacosamide added to one baseline AED in epilepsy patients with partial-onset seizures.

In the European Union, VIMPAT® 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.[1]

Brivaracetam is in phase 3 clinical development for the adjunctive treatment of partial-onset seizures in adults with epilepsy and is not approved by any regulatory authority. Top-line results from the most recent Phase 3 study are expected in the second half of 2014.

The following is a guide to 10 UCB-sponsored data presentations at the 11th ECE:

Lacosamide:

Platform presentation

[p047]: ***Lacosamide conversion to monotherapy: effects on partial-onset seizure frequency in a historical-controlled multicenter, double-blind, randomized trial***
Wechsler, R.T. et al.
Date: Tuesday 1st July
Session Info: Antiepileptic drugs 2

Best poster presentation

[p345]: ***Lacosamide added to a monotherapy in epilepsy patients with partial-onset seizures: final analysis of the VITOBA study***
Noack-Rink, M. et al.
Date: Tuesday 1st July
Session Info: Antiepileptic drugs 5

Poster presentations

[p561]: ***Tolerability of lacosamide conversion to monotherapy: a historical-controlled multicenter, double-blind, randomized trial***
Wechsler, R.T. et al.
Date: Wednesday 2nd July
Session Info: Antiepileptic Drugs 8

[p567]: ***Efficacy and safety of lacosamide as first adjunctive treatment for uncontrolled partial-onset seizures: a multicenter open-label trial***
Tzvetanov, P. et al.
Date: Wednesday 2nd July
Session Info: Antiepileptic Drugs 8

[p566]: ***Effects on quality of life of lacosamide as first and later adjunctive treatment for uncontrolled partial-onset seizures: a multicenter open-label trial***
Escartin, A. et al.
Date: Wednesday 2nd July
Session Info: Antiepileptic Drugs 8

[p344]: ***Long-term non-interventional study of lacosamide safety as add-on therapy in patients with epilepsy and uncontrolled partial-onset seizures***
Steinhoff, B.J. et al.
Date: Tuesday 1st July
Session Info: Antiepileptic Drugs 5

LCM-PRR-000327-062014

[p565]: ***Lacosamide for uncontrolled primary generalized tonic-clonic seizures: an open-label pilot study with 59-week extension***
Wechsler, R.T. et al.
Date: Wednesday 2nd July
Session Info: Antiepileptic Drugs 8

[p560]: ***Efficacy of adjunctive lacosamide (≤400 mg/day) in complex partial and secondary generalized seizures in adults with focal epilepsy: pooled analysis of three open-label extension trials***
Dimova, S. et al.
Date: Wednesday 2nd July
Session Info: Antiepileptic Drugs 8

Brivaracetam:

Platform presentation

[p008]: ***Brivaracetam population pharmacokinetics in children with epilepsy aged 1 month to 16 years***
Schoemaker, R. et al.
Date: Monday 30th June
Session Info: Antiepileptic Drugs 1

Best poster presentation

[p569]: ***Brivaracetam bioavailability/bioequivalence comparison between 10, 50, 75 and 100 mg tablets and 100 mg intravenous bolus in healthy volunteers***
Stockis, A. et al.
Date: Wednesday 2nd July
Session Info: Antiepileptic Drugs 9

About VIMPAT® (lacosamide)

Important Safety Information about VIMPAT® in the EU and EEA[1]

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 anti-epileptic 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 (≥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 (≥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 ≥3XULN 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: 25th April 2014.

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

About Epilepsy

Epilepsy is a chronic neurological disorder affecting approximately 65 million people worldwide and at least 6 million in Europe.[2,3] Anyone can develop epilepsy; it occurs across all ages, races and genders and is defined as two or more unprovoked seizures.[3,4]

References .

1. VIMPAT® EU Summary of Product Characteristics. Accessed 16th June 2014 from http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Product_Information/human/000863/WC500050338.pdf

2. The Epilepsy Foundation of America. Accessed 16th June 2014 from http://www.epilepsyfoundation.org/aboutepilepsy/

3. Epilepsy in the WHO European Region: Fostering Epilepsy Care in Europe. Report of the ILAE/IBE/WHO Global Campaign Against Epilepsy. August 2010. ISBN NR 978-90-810076-3-4. Accessed 16th June 2014 from http://www.ibe-epilepsy.org/downloads/EURO%20Report%20160510.pdf

4. NINDS/NIH. Seizures and Epilepsy. Accessed 16th June 2014 from http://www.ninds.nih.gov/disorders/epilepsy/detail_epilepsy.htm#196923109

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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 8500 people in approximately 40 countries, the company generated revenue of € 3.4 billion in 2013. 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.