UCB News

New data from UCB's epilepsy portfolio to be highlighted at the 67th Annual Meeting of the American Epilepsy Society

- UCB-sponsored data include the first presentation of investigational data of VIMPAT® (lacosamide) as monotherapy for the treatment of partial-onset seizures in adults with epilepsy

Brussels (Belgium), November 20th, 2013 – 0700 (CEST) – UCB, a global biopharmaceutical company focusing on CNS and immunology treatment and research, will be sponsoring 15 data presentations at the 67th Annual Meeting of the American Epilepsy Society in Washington, D.C., December 6–10. The poster presentations on VIMPAT® (lacosamide) C-V include investigational data evaluating VIMPAT® as monotherapy and further studies of VIMPAT® as add-on therapy for the treatment of partial-onset seizures in adults with epilepsy.

VIMPAT® is indicated as an adjunctive therapy for the treatment of partial-onset seizures in adults with epilepsy (ages ≥ 17 in the U.S., ages ≥ 16 years in the EU).[1,2] The most common adverse reactions reported in pivotal trials and occurring in 10 percent or more of VIMPAT®-treated patients, and greater than placebo, were dizziness, headache, nausea, and diplopia. Lacosamide is not currently approved as monotherapy. Additional important safety information for VIMPAT® is available below.[1,2]

"The multiple data sets being presented at this year's AES meeting demonstrate UCB's ongoing investment in epilepsy research as part of our long-standing commitment to address unmet needs of people living with epilepsy," said Professor Dr. Iris Loew-Friedrich, Chief Medical Officer and Executive Vice President, UCB. "We continue to work with experts in the scientific community to expand our understanding of the efficacy and safety of VIMPAT®, and we look forward to sharing the primary efficacy and safety data from our conversion to lacosamide monotherapy study of adults living with partial-onset seizures."

Investigational data will also be presented on brivaracetam, which is being studied as adjunctive therapy for the treatment of partial-onset seizures in adults with epilepsy. Additionally, results from three new epilepsy surveys, a study seeking to identify predictive factors for epilepsy management and an overview of a unique outcomes research partnership between academia and industry will be presented.

Following is a guide to UCB-sponsored data that will be presented during the AES annual meeting:

Lacosamide

Lacosamide Conversion to Monotherapy for the Treatment of Partial-Onset Seizures: Results from a Historical-Controlled, Multicenter, Double-Blind, Randomized Trial
Abstract 1.227; Poster Session 1; Saturday, December 7, 12 – 6 p.m.

Lacosamide added to an existing monotherapy in epilepsy patients with partial onset seizures: outcome of 2nd interim analysis of the VITOBA study (Vimpat added To One Baseline AED)
Abstract 1.218; Poster Session 1; Saturday, December 7, 12 – 6 p.m.

Lacosamide Has No Negative Effect on Sleep Parameters in Healthy Subjects: Results from an Open-Label Study
Abstract 2.145; Poster Session 2; Sunday, December 8, 8 a.m. – 5 p.m.

Lacosamide for Uncontrolled Primary Generalized Tonic-Clonic Seizures: An Open-Label Extension Study
Abstract 2.129; Poster Session 2; Sunday, December 8, 8 a.m. – 5 p.m.

Effect of Adjunctive Lacosamide on Complex Partial Seizures and Partial Seizures with Secondary Generalization in Adults: Pooled Analysis of Three Open-Label Extension Trials
Abstract 1.231; Poster Session 1; Saturday, December 7, 12 – 6 p.m.

Brivaracetam

Anticonvulsant Properties of Brivaracetam are not Mediated by its Effects on Voltage-Gated Sodium Channels
Abstract 1.204; Poster Session 1; Saturday, December 7, 12 – 6 p.m.

Safety/Tolerability of Adjunctive Intravenous (IV) Brivaracetam (BRV) as Infusion or Bolus in Patients with Epilepsy
Abstract 3.201; Poster Session 3; Monday, December 9, 8 a.m. – 3:30 p.m.

High Brain Permeability Differentiates Brivaracetam from Levetiracetam and Reveals

Promising Potential as Acute Intervention against Prolonged and Life-Threatening Seizures
Abstract 2.156; Poster Session 2; Sunday, December 8, 8 a.m. – 5 p.m.

Safety and Tolerability of Adjunctive Brivaracetam Administered As Oral Solution in Pediatric Patients Aged >1 Month to 16 Years with Epilepsy
Abstract 3.203; Poster Session 3; Monday, December 9, 8 a.m. – 3:30 p.m.

Brivaracetam is superior to levetiracetam in decreasing excitatory synaptic transmission
Abstract 1.207; Poster Session 1; Saturday, December 7, 12 – 6 p.m.

Epilepsy

Expert Opinion on Treatment of Idiopathic Generalized Epilepsy Syndromes of Childhood and Adolescence in Poland
Abstract 3.141; Poster Session 3; Monday, December 9, 8 a.m. – 3:30 p.m.

Expert Opinion on Treatment of Pediatric Status Epilepticus in Poland
Abstract 3.140; Poster Session 3; Monday, December 9, 8 a.m. – 3:30 p.m.

A Unique Partnership for Research in Epilepsy Outcomes: The Emory University and UCB Collaboration
Abstract 2.279; Poster Session 2; Sunday, December 8, 8 a.m. – 5 p.m.

Prevalence and Societal Impact of Epilepsy in Rwanda: Results of a Cross-Sectional Survey
Abstract 2.259; Poster Session 2; Sunday, December 8, 8 a.m. – 5 p.m.

Identifying the Clinical, Environmental and Genetic Predictive Factors for Epilepsy Management: The DICE Study
Abstract 1.304; Poster Session 1; Saturday, December 7, 12 – 6 p.m.

About Epilepsy[3,4,5]

Epilepsy is a chronic neurological disorder affecting approximately 65 million people worldwide and 3 million people in the U.S.—making it more common than autism, cerebral palsy, multiple sclerosis and Parkinson's disease combined. Anyone can develop epilepsy; it occurs across all ages, races and genders and is defined as two or more unprovoked seizures.

About VIMPAT®

VIMPAT® tablets and injection were launched in the U.S. in May 2009 as an add-on therapy for the treatment of partial-onset seizures in people with epilepsy who are aged 17 years and older. VIMPAT® injection is a short-term replacement when oral administration is not feasible in these patients. VIMPAT® oral solution was launched in June 2010. The availability of oral tablet, oral

solution and intravenous (IV) injection formulations permits flexibility in administration. Important safety information about VIMPAT® in the US is available below.[2]

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.[1]

Important Safety Information about VIMPAT® in the U.S.

Warnings and Precautions

Antiepileptic drugs (AEDs), including VIMPAT®, increase the risk of suicidal behavior and ideation. Patients taking VIMPAT® should be monitored for the emergence or worsening of depression, suicidal thoughts or behavior, and/or any unusual changes in mood or behavior. Patients and caregivers should also be advised to be alert for these behavioral changes and to immediately report them to the healthcare provider.

Patients should be advised that VIMPAT® may cause dizziness and ataxia. Therefore patients should not drive a car or operate complex machinery until they are familiar with the effects of VIMPAT® on their ability to perform such activities.

Dose-dependent PR interval prolongation has been observed in VIMPAT® clinical studies in patients and in healthy volunteers. When VIMPAT® is given with other drugs that prolong the PR interval, further PR prolongation is possible. Patients should be made aware of the symptoms of second-degree or higher AV block (e.g. slow or irregular pulse, feeling of lightheadedness and fainting) and told to contact their physician should any of these occur. VIMPAT® should be used with caution in patients with known cardiac conduction problems or with severe cardiac disease. In such patients, obtaining an ECG before beginning VIMPAT®, and after VIMPAT® is titrated to steady state, is recommended.

VIMPAT® administration may predispose to atrial arrhythmias (atrial fibrillation or flutter), especially in patients with diabetic neuropathy and/or cardiovascular disease. Patients should be made aware of the symptoms of atrial fibrillation and flutter (e.g. palpitations, rapid pulse, shortness of breath) and told to contact their physician should these symptoms occur.

Patients should be advised that VIMPAT® may cause syncope.

VIMPAT® should be gradually withdrawn (over a minimum of 1 week) to minimize the potential of increased seizure frequency.

Multiorgan hypersensitivity reactions have been reported with antiepileptic drugs. If this reaction is suspected, VIMPAT® should be discontinued.

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.

VIMPAT® (C-V) is a Schedule V controlled substance.

Common Adverse Reactions

In clinical trials, the most frequently seen adverse reaction with VIMPAT® was dizziness (31% vs 8% placebo). Other common adverse reactions occurring in ≥10 percent of VIMPAT®-treated patients, and greater than placebo, were headache, nausea, and diplopia.

Dosage adjustments are recommended for patients with mild or moderate hepatic impairment or severe renal impairment. Use in severe hepatic impairment patients is not recommended. Dose titration should be performed with caution in all renally and hepatically impaired patients.

In clinical trials, adverse reactions with intravenous administration generally appeared 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%).

For full prescribing information on VIMPAT®, visit http://www.vimpat.com/pdf/vimpat_PI.pdf (Accessed 17th October 2013)

For more information on VIMPAT®, visit www.Vimpat.com or contact UCB at 800.477.7877.

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

Important Safety Information about VIMPAT® in the EU and EEA

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 counselled to seek medical advice should any of these symptoms occur. Suicidal ideation and behavior have been reported in patients treated with anti-epileptic agents in several indications. Therefore patients should be monitored for signs of suicidal ideation and behaviors and appropriate treatment should be considered. Patients (and caregivers of patients) should be advised to seek medical advice should signs of suicidal ideation or behavior 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, vision blurred, vertigo, tinnitus, vomiting, constipation, flatulence, dyspepsia, dry mouth, pruritus, rash, muscle spasms, gait disturbance, asthenia, fatigue, irritability, injection site pain or discomfort (specific to solution for infusion), irritation (specific to solution for infusion), fall, and skin laceration. 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 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. Potential cases have been reported rarely with VIMPAT® and 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: 31st July 2013.

http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Product_Information/human/000863/WC500050338.pdf (Accessed 17th October 2013)

Notes to editors

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References

1. VIMPAT® European Summary of Product Characteristics http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Product_Information/human/000863/WC500050338.pdf (Accessed 17th October 2013)
2. VIMPAT® US Prescribing Information http://www.vimpat.com/PDF/vimpat_PI.pdf (Accessed 24th September 2013)
3. The Epilepsy Foundation of America. Available from: http://www.epilepsyfoundation.org/aboutepilepsy/whatisepilepsy/statistics.cfm. (Accessed 24th September 2013)
4. National Institute of Neurological Disorders and Stroke (NINDS) / National Institutes of Health (NIH). Seizures and Epilepsy. Available from: http://www.ninds.nih.gov/disorders/epilepsy/detail_epilepsy.htm#196923109. (Accessed 24th September 2013)
5. Epilepsy Foundation. About Epilepsy. http://www.epilepsyfoundation.org/aboutepilepsy/ (Accessed 17th October 2013)

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 9000 people in approximately 40 countries, the company generated revenue of EUR 3.4 billion in 2012. UCB is listed on Euronext Brussels (symbol: UCB).

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.