UCB News

New real-life and clinical data presented on VIMPAT® (lacosamide) at the 11th ECE

Brussels (Belgium), Monday 30th June, 2014 – 0700 (CEST) – UCB today announced data from two studies evaluating the efficacy and safety of VIMPAT® (lacosamide) as early adjunctive treatment in adults with partial-onset seizures. The results are presented this week at the 11th European Congress on Epileptology (ECE) in Stockholm, Sweden.

"The open-label and real-life data presented at ECE show that early adjunctive therapy with VIMPAT® can support patients with partial-onset seizures towards the goal of seizure freedom with manageable side effects." said Dr Plamen Tzvetanov from the Military Medical Academy, Pleven, Bulgaria.

Results from an open-label study showed that VIMPAT® as first adjunctive therapy was efficacious in achieving seizure freedom and was well-tolerated in patients with uncontrolled partial-onset seizures.[1] Final results from the VITOBA™ study showed that in clinical practice VIMPAT® improved partial-onset seizure control and was generally well-tolerated when used as adjunctive treatment to one baseline antiepileptic drug.[2]

Abstract title: Efficacy and safety of lacosamide as first adjunctive treatment for uncontrolled partial-onset seizures: a multicenter open-label trial

This open-label trial enrolled 456 patients with partial-onset seizures. Patients received lacosamide as first adjunctive therapy to a first monotherapy within 2 years of diagnosis, or as later add-on to 1-3 concomitant antiepileptic drugs, after 2 or more previous antiepileptic drugs, at ≥5 years since diagnosis. The primary efficacy variable was the proportion of patients achieving seizure freedom for the first 12 weeks of the 24 week maintenance phase.[1]

Of the 333 patients who completed 12 weeks' treatment, 19.8% were seizure-free. Among 96 patients who received lacosamide as first add-on, 72 completed 12 weeks' treatment and 68 patients completed 24 weeks. 37.5% of patients who completed 12-weeks' treatment and 26.5% of patients who completed 24-weeks' treatment were seizure-free for the respective treatment periods.[1]

Among 360 patients who received lacosamide as later add-on, 261 completed 12 weeks' treatment and 249 completed 24 weeks. 14.9% of patients who completed 12-weeks' treatment and 11.6% of patients who completed 24-weeks' treatment were seizure-free for the respective treatment periods.[1]

The most common treatment-emergent adverse events were dizziness (31.3% as first add-on, 33.6% as later add-on), somnolence (6.3% and 15.0%), and headache (13.5% and 11.4%).[1]

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Abstract title: Lacosamide added to a monotherapy in epilepsy patients with partial-onset seizures: final analysis of the VITOBA™ study

VITOBA™ was a 6-month, prospective, non-interventional study of the efficacy, safety and tolerability of lacosamide when added to a single antiepileptic drug in 573 adult patients with partial-onset seizures. Outcome variables included seizure freedom and reduction in seizure frequency at last study visit (6 months) compared with 3-month retrospective baseline, as well as treatment-emergent adverse events.[2]

During the study, 499 patients were treated with lacosamide up to 400 mg/day. During the final three months of the study (n=494), 72.5% of patients showed a ≥50% reduction in seizure frequency of who 45.5% were seizure free. Seizure freedom and ≥50% responder rates in patients aged 65 years or older were higher than in patients younger than 65 years. Seizure freedom and ≥50% responder rates were also higher for patients who received lacosamide after the first monotherapy compared with patients who had received more than one previous AED.[2]

The most common treatment-emergent adverse events judged by physicians to be related to lacosamide were fatigue (10.3%) and dizziness (8.8%).[2]

About VIMPAT® (lacosamide)

Important Safety Information about VIMPAT® in the EU and EEA[3]

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/

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References

1. Tzvetanov P, Waldman Zadeh W, Escartin A, *et al.* Efficacy and safety of lacosamide as first adjunctive treatment for uncontrolled partial onset seizures: a multicenter open-label trial. Abstract presented at the 11th European Congress on Epileptology, 29 June – 3 July, 2014, Stockholm, Sweden.
2. Noack-Rink M, Irrgang V, Ramirez F, *et al.* Lacosamide added to a monotherapy in epilepsy patients with partial-onset seizures: final analysis of the VITOBA study. Abstract presented at the 11th European Congress on Epileptology, 29 June – 3 July, 2014, Stockholm, Sweden.

3. 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

About UCB

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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.