News

New real world clinical data showed Vimpat® (lacosamide) effective in achieving seizure control in patients with refractory epilepsy

- At final follow-up 31.1% patients reported ≥50% seizures reduction and 9.8% were seizure free
- The probability of remaining on lacosamide was 80% at six months, 68% at one year and 45% at two years

Slough, UK, 5 July 2012 – Results published in the June online edition of Seizure from an independent multicentre study covering 19 epilepsy clinics in the UK showed that oral lacosamide administered as adjunctive therapy in refractory epilepsy is an effective and generally well-tolerated treatment, achieving seizure freedom for some patients.¹

“This is the largest independently reviewed and published cohort of patients on lacosamide”, said Dr Robert Elwes, Consultant Neurologist and Neurophysiologist, Department of Clinical Neurosciences, King’s College Hospital NHS Foundation Trust. “The results reflect real world experience with lacosamide and it is welcomed news that the outcomes are generally similar to those in the published randomised trials.”

The study included 403 adult patients with refractory epilepsy across 19 sites in the UK, in whom lacosamide had been prescribed as adjunctive therapy to a range of concomitant antiepileptic drugs (AEDs). Mean follow-up (FU) of patients was 11.6 months with the duration on lacosamide ranging from one day to 42 months. Ninety two percent (372/403) of patients presented with partial epilepsy and 79% (320/403) were taking two or more AEDs when lacosamide was added (mean=2.29, range 0-4).¹

The initial daily dose of lacosamide varied from 25 mg and 200 mg with 50 mg daily being the most frequent dose, and the mean maximum daily dose was 280mg.

The efficacy of lacosamide was evaluated at two time points: within three months of starting lacosamide (n=347), and within the last three months (n=285) of FU.¹

Results from the study indicated the following:¹

- Within the first three months 31.1% of patients (108/347) reported ≥50% seizure reduction and 9.2% (32/347) were seizure free
- At final FU 37.5% of patients (102/285) reported ≥50% seizure reduction and 9.8% (28/285) were seizure free
- The probability of remaining on lacosamide was calculated as 80% at six months, 68% at one year and 45% at two years

Adverse events (AEs) were reported in 48.7% of patients (193/403) with the most frequent being sedation, dizziness and nausea. 20.8% of patients (84/403) withdrew from the study due to intolerable AEs.¹

The key findings from this study of refractory patients in the everyday clinical setting are complementary to the pivotal trials data from a broadly similar population.
**About Epilepsy**

Epilepsy is a neurological disorder, characterised by the tendency to have recurrent seizures also known as fits which stem from the brain, unprovoked by an acute systemic or neurologic insult. In the UK it is estimated that 1 in 100 people have epilepsy equating to more than half a million of the population.²

**About Vimpat**

Vimpat® (film-coated tablets, solution for infusion and syrup) is indicated as adjunctive therapy in the treatment of partial-onset seizures with or without secondary generalisation in adult and adolescent (16-18 years) patients with epilepsy. Vimpat® solution for infusion may be used when oral administration is temporarily not feasible.³

The active substance, lacosamide (R-2-acetamido-N-benzyl-3-methoxypropionamide) is a functionalised amino acid.³

**Important safety information about Vimpat® in the EU and EEA**

Vimpat® (film-coated tablets, solution for infusion and syrup) is indicated as adjunctive therapy in the treatment of partial-onset seizures with or without secondary generalisation in adult and adolescent (16-18 years) patients with epilepsy. Vimpat® solution for infusion may be used when oral administration is temporarily not feasible. 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 lacosamide 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 lacosamide have been observed in clinical studies. Lacosamide 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 lacosamide is used in combination with products known to be associated with PR prolongation. Second-degree or higher AV block has been reported in post-marketing experience. In the placebo-controlled trials of lacosamide 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 lightheadedness 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 behavior have been reported in patients treated with antiepileptic agents. 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. The solution for infusion contains sodium, which should be taken into consideration for patients on a controlled sodium diet. Effects on ability to drive and use machines: Lacosamide may have minor to moderate influence on the ability to drive and use machines. Lacosamide 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 lacosamide on their ability to perform such activities. Laboratory abnormalities: Abnormalities in liver function tests have been observed in controlled trials with lacosamide 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 lacosamide 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 lacosamide and if multiorgan hypersensitivity reaction is suspected, lacosamide should be discontinued. Undesirable effects: The most common adverse reactions (≥10%) are dizziness, headache, diplopia, and nausea. 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.1 Refer to the Summary of Product Characteristics for other adverse reactions and full prescribing information. Date of revision: February 2012.

References

3. Vimpat Summary of product characteristics. Date of revision February 2012. Available at www.medicines.org.uk/EMC/medicine/21158/SPC/Vimpat+50+mg%2c+100+mg%2c+150+mg%2c+200+mg%2c+film-coated+tablets%2c+10+mg+ml+syrup%2c+solution+for+infusion/

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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 8 500 people in about 40 countries, the company generated revenue of EUR 3.2 billion in 2011. 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.