



## UCB launches Vimpat® in the U.S. for add-on treatment of epilepsy in adults

- **New antiepileptic drug with novel mechanism of action helps address critical unmet medical need for many people living with uncontrolled epilepsy**
- **Vimpat® (*lacosamide*)<sup>Ⓢ</sup> offers hope to people with epilepsy who still have uncontrolled partial-onset seizures with current treatment**

**Brussels, Belgium – 26 May 2009 – 6.00 PM CEST – press release, regulated information** – UCB today announced that Vimpat® (*lacosamide*)<sup>Ⓢ</sup>, a new antiepileptic drug (AED) is available in the U.S. as an add-on therapy for the treatment of partial-onset seizures in people with epilepsy who are 17 years and older. Vimpat® will be available in U.S. pharmacies by the first week of June 2009.

"The availability of Vimpat® in the U.S. is an important milestone for people living with epilepsy and for UCB," said Rich Denness, Vice-President and General Manager CNS U.S., UCB. "Bringing Vimpat® to U.S. patients underscores UCB's commitment to the epilepsy community and UCB's leadership position in this disease state."

Epilepsy affects approximately six million people in the U.S., Japan, U.K., France, Germany, Italy and Spain, and it can strike anyone at anytime.

"Lacosamide provides new hope in helping patients move closer to the goal of seizure freedom," said Steven S. Chung, MD, Director of Clinical Epilepsy Research at Barrow Neurological Institute in Phoenix. "Lacosamide can help patients across the treatment paradigm, from those recently diagnosed who have not achieved seizure control on current therapy, to those who have tried a variety of medications and are still suffering from frequent seizures."

### **The unmet medical need**

Epilepsy is a common neurological disorder that can be lifelong, and is difficult to control with a single drug:

- In a study of 525 people with epilepsy, less than half (47%) attained seizure control with the first AED
- More than 30% of patients will continue to experience seizures despite trying two or more AEDs

"Vimpat® has a novel mechanism of action, and has been studied in combination with multiple AEDs as well as several commonly used medications with no clinically significant pharmacokinetic drug interactions observed in clinical trials. This demonstrates the importance and potential utility of including Vimpat® in partial-onset epilepsy treatment regimens," said Kathleen Bos, MD, Vice-president, Medical Affairs, U.S., UCB.

While treatment with one drug remains the goal of AED therapy and provides adequate control to many patients, almost 40% of patients with epilepsy receive suboptimal seizure control on monotherapy. In these situations, a physician may prescribe different treatments until one is found to provide adequate seizure control for the patient.

However, some studies indicate that when primary therapy is well-tolerated, but does not provide adequate seizure control, adding an additional AED to the current one provides more seizure control than continually switching therapies.



### **Vimpat® approval based on clinical trials with approximately 1 300 patients**

The approval of Vimpat® is based on efficacy and safety data from one Phase II and two Phase III clinical trials with approximately 1300 adults with epilepsy who had uncontrolled partial-onset seizures. Before adding Vimpat®, patients experienced a median baseline seizure frequency ranging from 10 to 17 seizures per month, despite being on one to three other AEDs; and 45.2% of patients had previously tried seven or more AEDs to control their seizures.

In the studies, patients taking Vimpat® at 200mg and 400 mg/day experienced a median percent reduction in seizure frequency per 28 days of 33.3% and 36.8%, respectively, versus only 18.4% reduction in the placebo group. Additionally, 34.1% and 39.7% of patients taking Vimpat® at 200 mg and 400 mg/day, respectively, experienced ≥50% reduction in seizure frequency vs. only 22.6% in the placebo group.

More patients randomised to Vimpat® also experienced improvement in seizure freedom rates, compared with placebo. Across the pivotal trials, 3.3% of patients randomised to 400 mg/day of Vimpat® were seizure free throughout the 12-week maintenance phase, vs. 0.9% of placebo patients.

Seizure free days during the maintenance phase increased by a mean of 8% with 200 mg/day of Vimpat® and by 12% with 400 mg/day of Vimpat®, compared with 6% for placebo.

Patients began experiencing a reduction in seizures during the titration phase and maintained or had improved seizure control throughout the studies. The most common adverse events (≥10 percent in the Vimpat®-treated group and greater than placebo) reported in these trials included dizziness, headache, nausea, and diplopia. More than half of the patients completing the clinical trials opted to continue treatment, some for longer than five years.

Vimpat® demonstrated efficacy and tolerability when combined with a broad range of existing AEDs, and also provided efficacy regardless of the number of concomitant AEDs. Vimpat® was also studied with several commonly used medications, including digoxin, metformin, omeprazole, and an oral contraceptive (containing 0.03 mg ethinylestradiol and 0.15 mg levonorgestrel).

Vimpat® dosing should start at 50 mg twice daily and may be increased to a daily dose of 200 mg to 400 mg per day (recommended therapeutic dosing) administered in two divided doses. Vimpat® is available as oral tablets and as an intravenous (IV) infusion to allow for consistent treatment in an emergency room or hospital setting. These formulations are bio-equivalent, meaning doses do not need to be adjusted when converting from IV to oral. The IV formulation of Vimpat® does not require dilution prior to administration.

Vimpat® was approved by the U.S. Food and Drug Administration in October 2008 for the adjunctive treatment of partial-onset seizures in patients with epilepsy age 17 and over. Vimpat® has been designated as a Schedule V controlled substance by U.S. regulators.

In August 2008, the European Commission approved Vimpat® for the adjunctive treatment of partial-onset seizures with or without secondary generalization in patients with epilepsy age 16 and over. Vimpat® is available in Germany, the U.K., Greece, Austria, Denmark, Sweden, the Netherlands and Norway, with other European countries to follow.

### **Vimpat® offers new way of targeting pathways involved in seizures**

Pre-clinical studies indicate that Vimpat® has a novel mechanism of action, although the precise mechanism by which Vimpat® exerts its antiepileptic effect in humans is not yet clear.

In pre-clinical studies, the mechanism of action for Vimpat® has been shown to involve the modulation of sodium channel activity in the nervous system. Sodium channels play a crucial role in regulating the activity of the nervous system to help nerve cells communicate. Sometimes sodium channels are abnormally overactive and nerve cells become too excited, which may produce a seizure. The mechanism of action for Vimpat® is thought to reduce this sodium channel over-activity by enhancing the longer lasting inactive state of the channel, a different action compared with current sodium channel blocking drugs. This action then regulates the activity of over-excited nerve cells, which may contribute to the control of seizures.

Pre-clinical studies also suggest that Vimpat® binds to the collapsin response mediator protein-2 (CRMP-2), an important target that affects the way that nerves differentiate and grow. The precise nature of the interaction between Vimpat® and CRMP-2 and between CRMP-2 and seizure control is not known.

**For further information**

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**About epilepsy**

Epilepsy is a chronic neurological disorder affecting approximately 50 million people worldwide and three million people in the U.S.—making it more common than multiple sclerosis and Parkinson's disease combined. It is caused by abnormal, excessive electrical discharges of the nerve cells, or neurons, in the brain. Epilepsy is characterised by a tendency to have recurrent seizures and defined by two or more unprovoked seizures. There are many different seizure types and epileptic syndromes. Roughly 20-30% of people living with epilepsy have either uncontrolled seizures or significant side effects secondary to medication. This highlights the ongoing need for the development of new AEDs. For more information about epilepsy, visit [www.epilepsyadvocate.com](http://www.epilepsyadvocate.com) and [www.livebeyondepilepsy.com](http://www.livebeyondepilepsy.com).

**About UCB**

UCB, Brussels, Belgium ([www.ucb.com](http://www.ucb.com)) is a biopharmaceutical company dedicated to the research, development and commercialization of innovative medicines with a focus on the fields of central nervous system and immunology disorders. Employing approximately 10 000 people in over 40 countries, UCB generated revenue of EUR 3.6 billion in 2008. 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. Such statements are subject to risks and uncertainties that may cause actual results to be materially different 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, effects of future judicial decisions, changes in regulation, exchange rate fluctuations and hiring and retention of its employees.

**Important safety information about Vimpat® in the U.S.**

Vimpat® (lacosamide) is a medicine that is used with other medicines to treat partial-onset seizures in patients 17 years of age and older with epilepsy. Vimpat® is generally well-tolerated, but may not be for everyone. Patients should discuss with their doctor if Vimpat® is right for them.

The most common side effects with Vimpat® are dizziness, headache, nausea and blurred vision. Vimpat® may also cause problems with coordination and balance. Patients should not drive, operate machinery or do other dangerous activities until they know how Vimpat® affects them. Patients should not stop taking Vimpat® without first talking to their doctor. Stopping Vimpat® suddenly can cause serious problems. Vimpat® could make patients feel faint. Patients should tell their doctor if they have a heart condition or if they are taking other medicines that affect the heart. In rare cases, Vimpat® may cause reactions that could affect the heart, liver or kidney. The patient should contact their doctor immediately if they are tired, have jaundice (yellowing of skin or eyes), and have dark urine. Antiepileptic drugs, including Vimpat®, may cause suicidal thoughts or actions in a very small number of people, about 1 in 500. Patients should call their healthcare provider right away if they have new or worsening symptoms of depression, any unusual changes in mood or behavior, or suicidal thoughts, behavior, or thoughts about self harm that they have never had before or may be worse than before. To report SUSPECTED ADVERSE REACTIONS, contact UCB, Inc. at 1-866-822-0068 or FDA at 1-800-FDA-1088 or [www.fda.gov/medwatch](http://www.fda.gov/medwatch).

Please see additional patient information including the Vimpat® Medication Guide at the end of the full prescribing information on [www.Vimpat.com](http://www.Vimpat.com).

**Important safety information about Vimpat® in Europe**

Vimpat® is indicated as adjunctive therapy in the treatment of partial-onset seizures with or without secondary generalisation in patients with epilepsy aged 16 years and older. Vimpat® solution for infusion is an alternative for patients when oral administration is temporarily not feasible. Contraindications: Hypersensitivity to the active substance or to peanuts or soya or to 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. Suicidal ideation and behaviour have been reported in patients treated with anti-epileptic agents. 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. Undesirable effects: The most common adverse reactions (>10%) are dizziness, headache, diplopia, and nausea. Other common adverse reactions (1–10%) are depression, balance disorder, coordination abnormal, memory impairment, cognitive disorder, somnolence, tremor, nystagmus, vision blurred, vertigo, vomiting, constipation, flatulence, pruritus, gait disturbance, asthenia, fatigue, fall, and skin laceration. Refer to the European Summary of Product Characteristics for full prescribing information. <http://www.emea.europa.eu/humandocs/PDFs/EPAR/vimpat/H-863-PI-en.pdf> (Accessed 02.03.09)