

Vimpat® Approved in Europe

First New Epilepsy Treatment for Partial-Onset Seizures in Three Years

- A novel mode of action
- Improved seizure control when added to a wide range of antiepileptic drugs
- High long-term retention rate
- Multiple formulations for ease of use
- Soon to be launched in Germany and the UK

Brussels, BELGIUM – September 3, 2008 at 7:00 am CEST – press release, regulated information: UCB announced today that the European Commission (EC) has approved Vimpat® (*lacosamide*) 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® is the first new antiepileptic drug (AED) for partial-onset seizures in three years and offers a new treatment option for European patients living with uncontrolled partial-onset epilepsy.

Professor Elinor Ben-Menachem, Clinical Trial Investigator, Department of Clinical Neuroscience, Goteborg University, Sweden said, "Vimpat® offers new hope for improved seizure control in adult patients with partial onset seizures. The novel mode of action of Vimpat® makes it different from all other antiepileptic drugs currently available. Vimpat® should be considered a valuable treatment option for adult patients with partial-onset seizures who need additional seizure control."

Roch Doliveux, Chief Executive Officer, UCB said, "The approval of Vimpat® underscores the importance of UCB's continued drive to develop innovative medicines that improve lives. UCB is pleased to make this important new antiepileptic drug available to European physicians and patients."

A novel mode of action

Preclinical studies indicate that Vimpat® has a novel mode of action. While the precise mechanism by which Vimpat® exerts its antiepileptic effect in humans remains to be fully elucidated, in preclinical studies Vimpat® has been shown to modulate sodium channel activity differently compared with other sodium channel blocking AEDs. Sodium channels play a crucial role in regulating the activity of the nervous system to help nerve cells communicate. Sometimes sodium channels become abnormally overactive which may produce a seizure. Vimpat® mode of action is thought to reduce this sodium channel over-activity. The regulation of the activity of nerve cells may contribute to the control of seizures.

Preclinical studies also suggest that Vimpat® binds to the collapsin response mediator protein-2 (CRMP-2), a phosphoprotein which is mainly expressed in the nervous system and is involved in neuronal differentiation and control of axonal outgrowth. The nature of



the interaction between Vimpat® and CRMP-2 is not completely known. Vimpat® is the only AED known to interact with CRMP-2.

Improved seizure control when added to a wide range of antiepileptic drugs

The European Commission approval is based on data from three multicentre, randomized, placebo-controlled clinical trials that evaluated the efficacy and safety of Vimpat® adjunctive treatment in over 1,300 partial-onset seizure patients aged 16 years and older who were not adequately controlled with between one to three concomitant AEDs and with or without additional vagus nerve stimulation. Patients entering these trials were experiencing on average 10-15 seizures per month and most patients (84%) were uncontrolled on two to three AEDs.

In clinical trials Vimpat® improved seizure control when added to a wide range of first and second generation antiepileptic drugs. Pooled analysis shows that treatment with Vimpat® 200 mg/day and 400 mg/day reduced seizures by half in 34% and 40% of patients with partial-onset seizures, respectively, compared with 23% in the placebo group. Vimpat® was generally well tolerated with the most common adverse events ($\geq 10\%$ and greater than placebo) reported in these trials including dizziness, headache, nausea and diplopia.

High long-term retention rate

In a long-term study, patients treated with Vimpat® achieved sustained reductions in partial-onset seizures. Seventy seven per cent of 370 patients who took part in this open-label trial completed at least 12 months of Vimpat® treatment, 61% completed at least 24 months, and 56% completed at least 30 months of treatment.

Multiple formulations for ease of use

Vimpat® has been approved as oral tablet (50mg, 100mg, 150mg, 200mg), oral syrup (15mg/ml) and solution for infusion (10mg/ml), to allow for additional dosage formulation options. Vimpat® solution for infusion is an alternative for patients when oral administration is temporarily not feasible.

About Epilepsy

Epilepsy is a chronic neurological disorder affecting 50 million people worldwide. 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. Approximately, 20-30% of people living with epilepsy have uncontrolled seizures or significant side effects secondary to medication highlighting the ongoing need for the development of new antiepileptic drugs.

Further information

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About UCB

UCB (Brussels, Belgium, www.ucb-group.com) is a global leader in the biopharmaceutical industry dedicated to the research, development and commercialization of innovative medicines with focus on the fields of central nervous system and immunology disorders. Employing around 12 000 people in over 40 countries, UCB achieved revenue of EUR 3.6 billion in 2007. UCB is listed on Euronext Brussels (symbol: UCB).

**Forward looking statement**

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.