UCB's Vimpat® approved by U.S. FDA as adjunctive therapy for partial onset seizures in adults

- **New antiepileptic drug with a novel mechanism of action**
- **Vimpat® helped people with epilepsy who still had uncontrolled partial onset seizures with current treatment**
- **Vimpat® will be available in the U.S. as oral tablets and intravenous (IV) infusion**
- **Vimpat® should be launched in the U.S. early 2009 by the well-established UCB epilepsy team**

Brussels, BELGIUM, October 29, 2008 at 7:00 CET– press release, regulated information - UCB announced today that the U.S. Food and Drug Administration (FDA) has approved Vimpat® (lacosamide), a new antiepileptic drug (AED). Vimpat® is for use as an add-on therapy for the treatment of partial-onset seizures in people with epilepsy who are 17 years and older.

"Having a new antiepileptic drug option may offer adults with partial onset seizures the chance to obtain seizure control. There is still a need for new therapies to help patients achieve this goal," said lead investigator Steven S. Chung, MD, Director of Clinical Epilepsy Research at Barrow Neurological Institute in Phoenix. "Vimpat® is unique because it works unlike any other antiepileptic drug that is currently available. It should be considered for epilepsy patients who have uncontrolled seizures with their current treatment regimen—no matter how many previous antiepileptic drugs they've tried."

Epilepsy is a chronic neurological disorder affecting approximately three million people in the U.S. Less than half (47%) will attain seizure control with their first AED, and more than 30% will continue to experience seizures despite trying two or more AEDs.

"At UCB, we are thrilled that Vimpat® will be a new option for people with epilepsy in the U.S. living with uncontrolled partial onset seizures. Vimpat® confirms our proven commitment to the epilepsy community," said Roch Doliveux, CEO of UCB. "The approval of Vimpat® in the U.S. demonstrates that we are continuing to deliver on our strategy to provide innovative medicine for patients who suffer from severe diseases."

New Way of Targeting Pathways Involved in Seizure Onset

Preclinical studies indicate that Vimpat® has a novel mechanism of action. The precise mechanism by which Vimpat® exerts its antiepileptic effect in humans remains to be fully elucidated.

In preclinical studies, Vimpat®'s mechanism of action 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 become abnormally overactive and nerve cells become too excited, which may produce a seizure. Vimpat®'s mechanism of action is thought to reduce this sodium channel over-activity by prolonging

the longer lasting resting 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.

In preclinical studies, Vimpat® has also been shown to bind 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.

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 1,300 people with epilepsy age 16 and older 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 percent of patients had previously tried 7 or more AEDs to control their seizures. In the studies, patients randomized to Vimpat® had their seizures reduced by half and experienced reductions in median seizure frequency at rates that were significantly greater than those in placebo groups.

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

Vimpat® demonstrated efficacy and tolerability when combined with a broad range of existing AEDs.

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

Vimpat® dosing should start at 50mg twice daily and maybe increased to a daily dose of 200 to 400 mg per day (recommended therapeutic dosing) administered in two divided doses. Vimpat® will be available as oral tablets and as an intravenous (IV) infusion to allow for consistent treatment in a hospital setting. These formulations are bioequivalent, 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® oral solution is still under review by the FDA.

As with many other neurology products, Vimpat® will be designated a controlled substance. The recommended classification is still under review by authorities, however this is expected to be finalized in early 2009 at which time Vimpat® will be available in U.S. pharmacies.

At the end of 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. In September Vimpat® was launched in Germany and the UK with other European countries to follow in the coming months.

About Epilepsy in the U.S.

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 characterized 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 percent 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.epilepsyfoundation.org or www.epilepsy.com.

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

AEDs, including Vimpat®, increase the risk of suicidal behavior and ideation in patients taking these drugs. Patients should be monitored for the emergence or worsening of depression, suicidal thoughts, or behavior and/or any usual changes in mood or behavior. Patients should be advised that Vimpat® may cause dizziness, ataxia, and syncope. Caution is advised for patients with known cardiac conduction problems, who are taking drugs known to induce PR interval prolongation, or with severe cardiac disease. In patients with seizure disorders, Vimpat® should be gradually withdrawn to minimize the potential of increased seizure frequency. Multiorgan sensitivity reactions have been reported with anticonvulsants, if this reaction is suspected, Vimpat® should be discontinued and an alternative treatment started.

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.