



Newly-Published Study Reinforces Role of Antiepileptic Drug Vimpat® (Iacosamide) (C-V) as an Add-on Treatment that Significantly Reduces Partial-onset Seizures in Adults with Epilepsy

- Vimpat demonstrated significantly greater seizure reduction versus placebo when added to other antiepileptic drugs (AEDs).
- Absence of significant pharmacokinetic drug interactions, as demonstrated in this and other Vimpat studies, may allow for ease of Vimpat use as add-on therapy.

Atlanta – March 11, 2010 – press release – [UCB](#) today announced that the antiepileptic drug (AED) [Vimpat](#)® (Iacosamide) (C-V) demonstrated significantly fewer partial-onset seizures versus placebo in adults living with epilepsy, according to a Phase III clinical study published online in *Epilepsia*.

This study was one of three that supported the approval of Vimpat by the U.S. Food and Drug Administration (FDA) in 2008 for use as an add-on therapy for the treatment of partial-onset seizures in people with epilepsy who are 17 years and older. Previous studies have demonstrated that Vimpat has a novel mechanism of action. It is available as oral tablets and as an intravenous (IV) infusion to allow for consistent treatment in a hospital setting. Although Vimpat demonstrated clinical benefits at both doses in this study (400 and 600 mg/day), as measured by several efficacy endpoints, the maximum FDA-approved dose is 400 mg/day.

“This and other studies demonstrate Vimpat’s established efficacy and tolerability, with almost 3,000 patient years of exposure. In addition, no clinically significant pharmacokinetic drug interactions were observed in clinical trials when Vimpat was used in combination with seven different AEDs as well as several commonly used medications,” said James Zackheim, PhD, CNS Medical Director at UCB.

Uncontrolled seizures and medication side effects pose challenges to independent living, learning and employment, and the goal of [epilepsy](#) therapy is seizure freedom with minimal side effects. While treatment with one drug is ideal, fewer than half (47%) of newly-diagnosed patients become seizure-free with their first AED.

“My clinical and study experience with Vimpat reinforces its role in a new approach to epilepsy treatment. If a monotherapy is not effective, adding another AED may help some patients attain treatment success sooner, compared to a monotherapy-to-monotherapy approach,” said study author and lead Vimpat clinical trial investigator Steven Chung, MD, Director of Clinical Epilepsy Research at [Barrow Neurological Institute](#) at St. Joseph’s Medical Center in Phoenix.

Vimpat Demonstrated Significant Efficacy and Greater Rates of Seizure Freedom Versus Placebo

In this double-blind, placebo-controlled Phase III study, patients taking 400 and 600 mg/day of Vimpat had significantly greater reductions in seizure frequency per 28 days from baseline versus placebo (37.3% for Vimpat 400 mg/day [P=0.008] and 37.8% for Vimpat 600 mg/day [P=0.006], compared to 20.8% for placebo).



In addition, the 50 percent responder rate was 38.3% for those taking Vimpat 400 mg/day [$P < 0.001$] and 41.2% for those taking Vimpat 600 mg/day [$P < 0.001$], versus only 18.3% of patients taking placebo. The 50 percent responder rate is defined as the proportion of patients who experience a 50 percent or greater reduction in seizure frequency from baseline to maintenance period.

In a secondary analysis, more patients taking Vimpat achieved seizure freedom throughout the maintenance period compared to placebo. Among patients taking Vimpat 400 mg/day and 600 mg/day, 2.5% (4 patients out of 160) and 8.1% (5 patients out of 62), respectively, were seizure-free throughout the maintenance phase, compared to none of the placebo group patients.

In the study, the most common dose-related adverse events included dizziness (44.9%), nausea (13.3%), diplopia (13%), blurred vision (12.6%), headache (12.3%), vomiting (12.3%), and tremor (11%). Most adverse events were mild to moderate in intensity. These data are consistent with results from other clinical trials of Vimpat.

About the Study

Researchers in the United States enrolled 405 patients, aged 16 to 70 years, who had uncontrolled partial-onset seizures, with or without secondary generalization, for at least two years despite prior therapy with at least two AEDs. The objective of this trial was to evaluate the efficacy and safety of Vimpat doses of 400 mg/day and 600 mg/day. In the study, Vimpat was evaluated in combination with a broad range of AEDs with or without vagus nerve stimulation (VNS). The concomitant AEDs taken most frequently by patients in the study were levetiracetam, lamotrigine, carbamazepine, oxcarbazepine, phenytoin, topiramate, valproate, and zonisamide.

During the first eight weeks of the trial, researchers measured baseline seizure frequency rates. Patients were then randomized to receive Vimpat 400 mg/day, Vimpat 600 mg/day or placebo (along with prior AEDs), followed by a 6-week forced titration period. Patients were started on either placebo or Vimpat 100 mg/day. Patients in the Vimpat groups were then given increasing doses, in increments of 100 mg/day each week, until reaching the maintenance doses of either 400 mg/day or 600 mg/day. Patients remained on their final dosing schedule throughout the subsequent 12-week maintenance phase. The efficacy assessment was conducted on an intent-to-treat (ITT) basis that included all randomized patients who had received at least one dose of trial medication and had at least one post-baseline efficacy assessment. Efficacy was measured by:

Primary Endpoints

- The change in seizure frequency per 28 days from baseline to the maintenance period.
- The 50 percent responder rate, defined as the proportion of patients experiencing a 50 percent or greater reduction in seizure frequency from the baseline to the maintenance period.

Secondary Endpoints

- The percent change in seizure frequency per 28 days from baseline to the maintenance period.
- The 75 percent responder rate.
- The number and proportion of patients achieving seizure-free status throughout the maintenance period for patients completing the maintenance period.
- The percentage of seizure-free days during the maintenance period for patients entering the maintenance period.
- The change in seizure frequency and 50 percent responder rate differentiated by seizure type.



The 600 mg/day dose is not approved by the FDA. In clinical trials, the overall effect of the 600 mg/day dose was similar to the 400 mg/day dose, and was associated with higher incidence of adverse reactions.

IMPORTANT SAFETY INFORMATION

Vimpat is generally well-tolerated, but may not be for everyone. Patients should discuss with their doctor if Vimpat is right for them.

Warnings and Precautions

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. 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 tell their doctor if they have a heart condition or if they are taking other medicines that affect the heart. Vimpat could make patients feel faint. Patients should not stop taking Vimpat without first talking to their doctor. Stopping Vimpat suddenly can cause serious problems. 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.

Common Adverse Reactions

The most common side effects with Vimpat are dizziness, headache, nausea, and double vision.

To report SUSPECTED ADVERSE REACTIONS, contact UCB, Inc. at 866-822-0068 or FDA at 1-800-FDA-1088 or 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.

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. More than one million U.S. patients continue to experience seizures despite trying two or more antiepileptic drugs (AEDs).

Epilepsy 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 30 percent of people living with epilepsy have either uncontrolled seizures or significant side effects secondary to medication. Almost 60 percent of all epileptic seizures are partial onset.

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About UCB

UCB, Brussels, Belgium (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 more than 9,000 people in over 40 countries, UCB produced revenue of EUR 3.1 billion in 2009. UCB is listed on Euronext Brussels (symbol: UCB). U.S. headquarters is located in Atlanta.

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.

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