



New Studies Support Use of Intravenous Vimpat® (Iacosamide) (C-V) in Hospital and Emergency Settings

Data presented at the American Epilepsy Society annual meeting provide insights into initiating and monitoring intravenous treatment, and smoothly transitioning patients to oral Vimpat

Atlanta, December 7, 2009 – Results of two new studies support the use of the intravenous formulation of the antiepileptic drug (AED) Vimpat® for patients requiring add-on therapy in clinical settings where oral AED therapy is temporarily not feasible. These data, which were presented by UCB at the 63rd annual meeting of the American Epilepsy Society in Boston, further clarify the role of intravenous Vimpat in the institutional setting.

One study shows that patients can be transitioned from intravenous Vimpat to the oral formulation, while maintaining steady, therapeutic plasma levels.

“This study shows that intravenous Vimpat is generally well tolerated across a range of doses and infusion durations as a replacement for oral therapy in add-on epilepsy therapy. This will help patients receive Vimpat in clinical settings where administration of an oral epilepsy therapy is not possible, such as emergency rooms or those related to surgery,” said study author Gregory Krauss, MD, Department of Neurology, Johns Hopkins Epilepsy Center in Baltimore, MD. “This study helps clinicians understand what to expect when initiating and monitoring intravenous treatment in patients who are Vimpat-naïve or who need to substitute oral Vimpat with an intravenous formulation.”

A second study provides data on administration of a single intravenous loading dose of Vimpat over 15 minutes, followed by the equivalent daily oral dose administered twice daily.

Vimpat was launched in the U.S. in May 2009 as an add-on therapy for the treatment of partial-onset seizures in people with epilepsy who are 17 years and older. Vimpat has a novel mechanism of action that is different from all currently available AEDs. Vimpat is available as oral tablets and as an intravenous (IV) infusion to allow for consistent treatment in a hospital or emergency setting.

Vimpat can be initiated with either oral or intravenous administration. The initial dose should be 50 mg twice daily (100 mg per day). Vimpat can be increased weekly by 100 mg/day, given as two divided doses, up to the recommended maintenance dose of 200 to 400 mg/day. When switching from oral Vimpat, the initial total daily intravenous dosage of Vimpat should be equivalent to the total daily dosage and frequency of oral Vimpat and should be infused intravenously over a period of 30 to 60 minutes. At the end of the intravenous treatment period, the patient may be switched to Vimpat oral administration at the equivalent daily dosage and frequency of the intravenous administration.



Summary of Intravenous Vimpat Data Presented at 2009 AES Annual Meeting

Abstract: Pharmacokinetic evaluation of intravenous lacosamide as short-term replacement for oral lacosamide in partial-onset seizures

In this 160-patient analysis of the lacosamide long-term open-label extension trial, patients receiving oral lacosamide were converted to therapeutically equivalent intravenous doses, and grouped into three cohorts based on infusion duration. Results showed that intravenous lacosamide provided similar plasma concentrations as those associated with oral lacosamide, across consecutive dosing days and regardless of infusion durations.

- Average C_{trough} and C_{max} plasma concentrations (minimum and maximum concentrations of a drug in the body after dosing) for oral and intravenous lacosamide appeared dose-proportional across consecutive dosing days within a therapeutic dose range.
- Plasma concentration levels were similar across all cohorts.

Poster Session 2, Sunday, December 6, 4:00 pm – 5:00 pm (Abstract 2.223)

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Abstract: A multicenter, open-label trial to assess the safety and tolerability of a single intravenous loading dose of lacosamide followed by oral maintenance as adjunctive therapy in subjects with partial-onset seizures: an interim report

In this study, patients currently taking one to two AEDs were grouped into three, 25-patient cohorts and given three progressively increasing doses of intravenous lacosamide (200 mg, 300 mg and 400 mg) administered via 15-minute infusions, followed by the same dose of the oral form given twice-daily for 6.5 days.

The first three cohorts (200 mg, 300 mg and 400 mg loading dose) have completed the trial. All subjects in the first cohort (200 mg loading dose) completed the trial. One subject (4 percent) from the second cohort (300 mg loading dose) and four subjects (16 percent) from the third cohort (400 mg loading dose) withdrew due to adverse events.

Based on results of these cohorts, enrollment of the fourth repeat cohort will proceed with the highest well-tolerated loading dose. Additional data on safety and tolerability will be presented during the poster session at AES.

Poster Session 2, Sunday, December 6, 4:00 pm – 5:00 pm, Hall D, Level 2 (Abstract 2.222)

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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 double 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.

Please see additional patient information including the Vimpat® Medication Guide at the end of the full prescribing information on <http://www.vimpat.com/pdfs/PI.pdf>.

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Further information

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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 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.

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