

## ***Epilepsia* study demonstrates new add-on antiepileptic drug VIMPAT<sup>®</sup> (lacosamide) significantly reduces partial-onset seizures in adults with epilepsy**

- Vimpat<sup>®</sup> demonstrated greater seizure reduction and improved seizure freedom versus placebo when added to first and second-generation antiepileptic drugs (AEDs)
- Phase III study supports recent U.S. FDA and European Commission approvals of Vimpat<sup>®</sup>

**Atlanta, GA – January 27, 2009 – press release –** The new antiepileptic drug Vimpat<sup>®</sup> (lacosamide) demonstrated significantly fewer seizures in adult partial-onset epilepsy patients whose seizures were inadequately controlled despite taking up to three other AEDs, according to a Phase III clinical study published online in *Epilepsia*.

In the study, seizure reduction 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 partial seizure frequency per 28 days from the baseline to the maintenance period.

### *Secondary Endpoints*

- Seizure freedom:
  - The number and proportion of patients achieving seizure-free status throughout the maintenance period for patients completing the maintenance period.
  - The proportion of seizure-free days during the maintenance period for patients entering the maintenance period.

Vimpat<sup>®</sup> was recently approved by the U.S. Food and Drug Administration (FDA) for use as an add-on therapy for the treatment of partial-onset seizures in adult patients with epilepsy. Earlier this year, the European Commission approved Vimpat<sup>®</sup> for the adjunctive treatment of partial-onset seizures with or without secondary generalization in adult patients with epilepsy.

“These results are particularly encouraging given the number of people with epilepsy who, despite current therapies, still face the challenge of living with uncontrolled seizures,” said lead study author Professor Péter Halász, MD, PhD, National Institute of Psychiatry and Neurology, Neurology Department, Budapest. “Vimpat<sup>®</sup> showed significant efficacy versus placebo in a challenging clinical trial patient population.”



In the study, 87 percent of patients were taking at least two AEDs and 37 percent were taking three AEDs. Although they were already taking multiple AEDs, patients enrolled in the trial were still experiencing 9.9 - 11.5 seizures per 28 days at baseline.

### **Patients who Added Vimpat<sup>®</sup> to Their Treatment Plan Experienced Fewer Seizures**

In the double-blind, placebo-controlled Phase III study, patients began experiencing a reduction in seizures during the titration period and maintained or improved seizure control throughout the study. Vimpat<sup>®</sup> significantly reduced seizure frequency per 28 days from baseline versus placebo (20.5 percent for placebo, 35.3 percent for Vimpat<sup>®</sup> 200 mg/day [P=0.02], and 36.4 percent for Vimpat<sup>®</sup> 400 mg/day [P=0.03]).

In addition, a higher rate of patients experienced a 50 percent or greater reduction in seizure frequency. Significantly more patients responded to Vimpat<sup>®</sup> 400 mg/day than placebo (40.5 percent had seizures reduced by at least half versus 25.8 percent, respectively [P=0.01]), and numerically more patients responded to Vimpat<sup>®</sup> 200 mg/day than placebo (35.0 percent had seizures reduced by at least half versus 25.8 percent, respectively [P=0.07]).

Vimpat<sup>®</sup> patients who completed the maintenance phase of the study also experienced more complete seizure freedom than those in the placebo group. Among patients taking Vimpat<sup>®</sup> 200 mg/day and 400 mg/day, 3.6 percent and 2.4 percent, respectively, were seizure-free throughout the maintenance phase, compared to 2.1 percent of patients in the placebo group.

In the study, the most commonly reported treatment-emergent adverse events were dizziness (4.9 percent for placebo, 10.4 percent for Vimpat<sup>®</sup> 200 mg/day and 15.7 percent for Vimpat<sup>®</sup> 400 mg/day), headache (7.4 percent, 11.0 percent and 8.2 percent, respectively) and diplopia (1.2 percent, 8.0 percent and 10.1 percent, respectively). Most adverse events were mild to moderate in intensity. These data are consistent with results from other clinical trials of Vimpat<sup>®</sup>.

### **About the Study**

Researchers in Europe and Australia enrolled 485 patients, aged 16 to 70 years, who had uncontrolled partial-onset seizures, with or without secondary generalizations, 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 lacosamide doses of 200 mg/day and 400 mg/day. In the study, Vimpat<sup>®</sup> was evaluated in combination with a broad range of both first and second generation AEDs. The five concomitant AEDs taken most frequently by patients in the study were carbamazepine, valproate, lamotrigine, topiramate, and levetiracetam. The mean number of years since diagnosis of epilepsy was 22.3 (± 12.56 years).



During the first eight weeks of the trial, researchers measured baseline seizure frequency rates. Patients were then randomized to receive Vimpat® 200 mg/day, Vimpat® 400 mg/day or placebo (along with prior AEDs), followed by a four-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 200 mg/day or 400 mg/day. The Vimpat® 200 mg/day group received placebo for first 2 weeks to allow all patients to reach the target maintenance dose simultaneously. 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.

Patients completing the maintenance period were eligible to enter an open-label lacosamide extension trial.

### **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 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.

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

Vimpat® tablets are indicated as adjunctive therapy in the treatment of partial-onset seizures in patients with epilepsy who are 17 years and older. Vimpat® injection is indicated as short-term replacement when oral administration is not feasible in these patients. 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 hypersensitivity reactions have been reported with antiepileptic drugs. If this reaction is suspected, treatment with Vimpat® should be discontinued.



AEDs increase the risk of suicidal behavior and ideation. Patients taking Vimpat® should be monitored for the emergence or worsening of depression, suicidal thoughts or behavior, and/or any unusual changes in mood or behavior.

The most common adverse reactions occurring in >10 percent of Vimpat®-treated patients, and greater than placebo, were diplopia, headache, dizziness, and nausea.

Vimpat® will be designated a controlled substance. The recommended classification is still under review by authorities.

Please go to <http://www.fda.gov/cder/foi/label/2008/022253lbl.pdf> for approved prescribing information.

### **Further Information**

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