



UCB receives CHMP positive opinion on Keppra® for infants and young children with partial-onset epilepsy

European marketing approval recommended for Keppra® (*levetiracetam*) as adjunctive treatment of partial-onset seizures in infants and young children aged one month to under four years

Brussels (Belgium), 23rd July, 2009 - press release - UCB announced today that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has issued a positive opinion recommending that the European Commission grant marketing authorisation for Keppra® as adjunctive treatment of partial-onset seizures in infants and young children aged one month to under four years.

The CHMP decision is based on the results of a Phase III, double-blind, randomised, multi-centre, placebo-controlled study evaluating the efficacy and tolerability of Keppra® oral solution (20-50 mg/kg/day) in 116 paediatric patients with refractory partial-onset seizures, aged from one month to under four years. Infants and children in this study were experiencing partial-onset seizures with or without secondary generalisation that were inadequately controlled despite treatment with one or two other antiepileptic drugs.

"This is the first well-controlled study providing information on the efficacy and tolerability of *levetiracetam* in infants and young children with inadequately controlled partial-onset seizures. The results of this study suggest that *levetiracetam* will be a valuable new treatment option in very young patients with partial-onset epilepsy." said Associate Professor Jesus Eric Pina-Garza, Children's Hospital at Vanderbilt, Nashville, Tennessee, U.S.

In this clinical trial Keppra® was shown to significantly reduce the frequency of partial-onset seizures with 43.1% of Keppra®-treated patients experiencing at least a 50% reduction in seizure frequency during the evaluation period (five days) compared with 19.6% of placebo-treated patients (p=0.013). Keppra® was generally well-tolerated in this paediatric population. The most commonly reported treatment-emergent adverse events (>5%) that occurred more frequently in the Keppra® group were somnolence (13.3% vs. 1.8% for placebo) and irritability (11.7% vs. 0% for placebo).

"For parents of very young children with partial-onset seizures that are poorly controlled with their current medication, the CHMP positive opinion is encouraging news. We look forward to the final determination of the European Commission and extending the availability of Keppra® as adjunctive therapy to children from one month to under four years with partial-onset seizures", said Troy Cox, President, CNS Operations, UCB.

Since its first launch in 1999, an innovative research and clinical trials programme has enabled Keppra® to realise its potential as a broad spectrum antiepileptic drug. As a result, it is available for a range of seizure types and in a range of formulations (250 mg, 500 mg, 750 mg and 1 000 mg tablets, 100 mg/ml oral solution and 100 mg/ml concentrate for solution for infusion, an alternative for patients when oral administration is temporarily not feasible).

In Europe Keppra® is approved as:



- Monotherapy in the treatment of partial-onset seizures with or without secondary generalization in patients from 16 years of age with newly diagnosed epilepsy
- Adjunctive therapy in the treatment of partial-onset seizures with or without secondary generalization in adults and children from four years of age with epilepsy
- Adjunctive therapy in the treatment of myoclonic seizures in adults and adolescents from 12 years of age with juvenile myoclonic epilepsy
- Adjunctive therapy for the treatment of primary generalised tonic clonic seizures in adults and adolescents from 12 years of age with idiopathic generalised epilepsy

Keppra® provided the foundation for UCB's growing epilepsy franchise which has now been extended to include Vimpat® (*lacosamide*) which is marketed in Europe as adjunctive therapy for the treatment of partial-onset seizures with or without secondary generalization in patients with epilepsy, aged 16 years and older and in the U.S. as adjunctive therapy in the treatment of partial-onset seizures in patients with epilepsy, aged 17 years and older. In the U.S. Vimpat® is a Schedule V controlled substance. Also, in the U.S. in 2008, Keppra® XR was approved as an add-on to other antiepileptic treatments for people with partial-onset seizures aged 16 years of age and over.

Further information

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Notes to Editors

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 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 and effective classification guides treatment and prognosis.

About Keppra® in Europe

Keppra® film coated tablets were first approved Europe in 2000 as adjunctive therapy in the treatment of partial-onset seizures with or without secondary generalization in patients with epilepsy, aged 16 years and older. Since this time, Keppra® has received several additional indications.

Please refer to the European Summary of Product Characteristics for full prescribing and safety information:

<http://www.emea.europa.eu/humandocs/PDFs/EPAR/keppra/H-277-PI-en.pdf> (accessed 19.06.09)

About Vimpat® in Europe

Please refer to the European Summary of Product Characteristics for full prescribing and safety information:

<http://www.emea.europa.eu/humandocs/PDFs/EPAR/vimpat/H-863-PI-en.pdf>

Important U.S. Keppra® Safety Information

Keppra® tablets and oral solution are indicated as adjunctive therapy in the treatment of partial onset seizures in adults and children 4 years of age or older with epilepsy, myoclonic seizures in adults and adolescents 12 years of age and older with juvenile myoclonic epilepsy, and primary generalized tonic-clonic seizures in adults and children 6 years of age and older with idiopathic generalized epilepsy.



Antiepileptic drugs (AEDs) increase the risk of suicidal thoughts or behavior in patients taking these drugs for any indication. Patients treated with any AED for any indication should be monitored for the emergence or worsening of depression, suicidal thoughts or behavior, and/or any unusual changes in mood or behavior.

Keppra® tablets and oral solution are associated with the occurrence of central nervous system adverse events including somnolence and fatigue, behavioral abnormalities, and coordination difficulties, as well as hematological abnormalities. In pediatric patients 4-16 years of age experiencing partial onset seizures, the most common adverse events associated with Keppra® in combination with other AEDs were somnolence, accidental injury, hostility, nervousness and asthenia. In adults experiencing partial onset seizures, the most common adverse events associated with Keppra® in combination with other AEDs were somnolence, asthenia, infection and dizziness. In patients 12 years of age and older experiencing myoclonic seizures with juvenile myoclonic epilepsy, the most common adverse events associated with Keppra® in combination with other AEDs were somnolence, neck pain, and pharyngitis. In patients 6 years of age and older experiencing PGTC seizures with idiopathic generalized epilepsy, the most common adverse event associated with Keppra® in combination with other AEDs was nasopharyngitis.

Keppra® injection is indicated as adjunctive therapy in the treatment of partial onset seizures in adults with epilepsy, myoclonic seizures in adults with JME, and PGTC seizures in adults with idiopathic generalized epilepsy. Keppra® injection is an alternative for patients when oral administration is temporarily not feasible. The adverse events that result from Keppra® injection use include all of those associated with Keppra® tablets and oral solution.

Keppra® XR extended-release tablets are indicated as adjunctive therapy in the treatment of partial-onset seizures in patients 16 years of age and older with epilepsy. Keppra XR™ causes somnolence, dizziness, and behavioral abnormalities. The most common adverse reactions observed with Keppra® XR in combination with other AEDs were somnolence and irritability. The adverse reactions that may be seen in patients receiving Keppra® XR are expected to be similar to those seen in patients receiving immediate-release Keppra® tablets. Keppra® XR should be gradually withdrawn to minimize the potential of increased seizure frequency.

For all Keppra® formulations, dosing must be individualized according to the patient's renal function status. In patients with end-stage renal disease on dialysis, it is recommended that immediate-release Keppra® be used instead of Keppra XR™.

Please see www.Keppra.com for U.S. full prescribing information and Medication Guide. Please see www.keppraxr.com for U.S. full prescribing information and Medication Guide.

Important U.S. Vimpat® safety information

Vimpat® (lacosamide C-V) 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 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 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 about 10 000 people in over 40 countries, UCB achieved revenues of EUR 3.6 billion in 2008. 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.