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Press Release

MORE EUROPEAN PATIENTS WITH EPILEPSY TO BENEFIT FROM KEPPRA®

EC approves new indication for Keppra® as adjunctive therapy in the treatment of primary generalised tonic-clonic seizures in patients with Idiopathic Generalised Epilepsy

Brussels (BELGIUM), 16 January 2007 - 5:30 PM (CET) – The European Commission (EC) has approved Keppra® (levetiracetam), as adjunctive therapy for the treatment of primary generalised tonic-clonic (PGTC) seizures in adults and adolescents from 12 years of age with Idiopathic Generalised Epilepsy (IGE). This new indication represents the fifth EU approval for Keppra® in epilepsy, and the second EU approval for Keppra® in a generalised seizure type.

Keppra® is already indicated in Europe as[1]:

- Monotherapy in the treatment of partial onset seizures with or without secondary generalisation in patients from 16 years of age with newly diagnosed epilepsy
- Adjunctive therapy for partial onset seizures with or without secondary generalisation in adults and children from 4 years of age with epilepsy
- Adjunctive therapy for myoclonic seizures in adults and adolescents from 12 years of age with Juvenile Myoclonic Epilepsy (JME).

'PGTC seizures are the most serious seizure type within the generalised epilepsies. In the well-controlled trial supporting this indication, relatively high PGTC seizure freedom rates were observed with Keppra® in previously drug refractory patients. This significant new approval supports a broad spectrum of efficacy, and adds to the growing data and patient experience with Keppra® as adjunctive therapy across partial and generalised seizure types.' said Professor Perucca, University of Pavia, Italy.

Clinical Data

The efficacy and tolerability of Keppra® in patients with refractory idioipathic generalised epilepsy (IGE) experiencing PGTC seizures has been demonstrated in a clinical trial presented at the 60th Annual Meeting of the American Epilepsy Society in San Diego, U.S., December 2006.

The study was a 24-week double-blind, placebo-controlled study of adjunctive Keppra® including 164 patients, age four to 65 years (adults, adolescents and a limited number of children) experiencing refractory idiopathic generalized epilepsy with ≥3 PGTC seizures over an eight week baseline. Keppra® was up-titrated over four weeks to a target dose of 3000 mg/day (60 mg/kg/day for paediatric patients), and the target dose was then evaluated over 20 weeks.[2] More patients receiving Keppra® in this study experienced at least a 50% reduction in PGTC seizure frequency per week compared with placebo (72.2% versus 45.2%; *p<0.001*).[2] High seizure freedom rates for patients taking Keppra® compared to those taking placebo were also observed over the treatment period (24.1% versus 7.1% (*p=0.004*)[2]. Keppra® was well tolerated and fatigue was the adverse effect most commonly reported. With continued long-term treatment, 47.4% and 31.5% of patients taking Keppra® were free of tonic-clonic seizures for at least 6 months and 1 year, respectively.[1]

'*Since Keppra® was launched in 2000, as adjunctive therapy for partial onset seizures, the clinical development program has focused on an ever widening range of seizure types. This latest approval for Keppra® is a further step towards our goal of seizure freedom, with minimal side effects, for as many people with epilepsy as possible*,' said Troy Cox, President CNS Operations, UCB.

About Keppra® in Europe[1]

Keppra® is indicated as monotherapy in the treatment of partial onset seizures with or without secondary generalisation in patients from 16 years of age with newly diagnosed epilepsy; as adjunctive therapy in the treatment of partial onset seizures with or without secondary generalisation in adults and children from 4 years of age with epilepsy; as adjunctive therapy in the treatment of myoclonic seizures in adults and adolescents from 12 years of age with JME and as adjunctive therapy in the treatment of PGTC seizures in adults and adolescents from 12 years of age with IGE. In monotherapy the most commonly reported side effects were fatigue and somnolence. As adjunctive therapy in adults with partial onset seizures the most commonly reported side effects were somnolence, asthenia and dizziness. As adjunctive therapy in paediatric patients (4-16 years of age) with partial onset seizures the most commonly reported side effects were somnolence, hostility, nervousness, emotional lability, agitation, anorexia, asthenia and headache. In adults and adolescents with myoclonic seizures the most common reported side effects associated with Keppra® in combination with other AEDs were headache and somnolence. In adults and adolescents with primary generalised tonic-clonic seizures the most common reported side effects associated with Keppra® in combination with other AEDs was fatigue. Keppra® is also indicated for intravenous administration and is available as 100 mg/mL concentrate for solution for infusion. The most common adverse events from Keppra® intravenous use were dizziness, somnolence, headache and postural dizziness. Please consult local prescribing information.

About Keppra® in the US[3]

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 and older with epilepsy and as adjunctive therapy in the treatment of myoclonic seizures in adults and adolescents 12 years of age and older with juvenile myoclonic epilepsy. Keppra® is associated with the occurrence of central nervous system adverse events including somnolence and fatigue and behavioral abnormalities, as well as hematological abnormalities. In adults experiencing partial onset seizures, Keppra® is also associated with coordination difficulties. In pediatric patients 4-16 years of age experiencing partial onset seizures, the most common adverse events associated with Keppra® in combination with other antiepileptic drugs (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 adults and adolescents 12 years of age and older with juvenile myoclonic epilepsy, the most common adverse events associated with Keppra® in combination with other AEDs were somnolence, neck pain and pharyngitis. Keppra® is also available as an intravenous formulation for the adjunctive treatment of partial-onset seizures in adults with epilepsy. Keppra®

injection is an alternative for patients when oral administration is temporarily not feasible. The adverse events that may result from Keppra® injection use for partial onset seizures include all those associated with Keppra® tablets and oral solution. For the U.S., prescribing information is available at www.keppra.com.

About UCB

UCB (www.ucb-group.com) is a leading global biopharmaceutical company dedicated to the research, development and commercialisation of innovative pharmaceutical and biotechnology products in the fields of central nervous system disorders, allergy/respiratory diseases, immune and inflammatory disorders and oncology – UCB focuses on securing a leading position in severe disease categories. Employing over 8,300 people in over 40 countries, UCB achieved revenue of 2.3 billion euro in 2005. UCB is listed on the Euronext Brussels Exchange. Worldwide headquarters are located in Brussels, Belgium.

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References

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2. Andermann E, Andermann F, Meyvisch P, Tonner F. Efficacy and tolerability of levetiracetam add-on therapy in patients with refractory idiopathic generalised epilepsy. Epilepsia 2006:47 (Suppl 4):187
3. U.S. Prescribing Information (available at www.Keppra.com)