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Press Release

European Commission Approves Keppra® for Use as Adjunctive Therapy in the Treatment of Myoclonic Seizures in Patients with Juvenile Myoclonic Epilepsy

Brussels (Belgium) - May 15, 2006 - Today UCB announced that the European Commission has approved the use of Keppra® (levetiracetam) as adjunctive therapy in the treatment of myoclonic seizures in adults and adolescents from 12 years of age with Juvenile Myoclonic Epilepsy (JME). Keppra® is the first and only newer anti-epileptic drug approved in Europe for the treatment of myoclonic seizures in JME.

"Keppra® has over one million patient years' experience and continues to help many people with partial-onset seizures. This new indication supports Keppra®'s established efficacy and we are pleased that Keppra® is now available to patients with myoclonic seizures in JME", said Troy Cox, President CNS Operations, UCB.

JME is a common epilepsy syndrome that usually starts between the ages of 12 and 18 and accounts for about 10% of all cases of epilepsy.[1] It is characterized by myoclonic jerks that occur in 100% of cases, with many patients also experiencing generalized tonic-clonic and absence seizures.[2,3] JME is frequently mis-diagnosed and this can lead to inappropriate treatment choices.[4,5]

Dr Soheyl Noachtar, Head of the Epilepsy Centre, University of Munich, Germany, welcomed the new indication for Keppra® (levetiracetam):
"*In JME there is a need for AEDs that are well-tolerated and do not aggravate seizures. Keppra® helps to fulfil this niche with its proven efficacy and tolerability in treating myoclonic seizures in patients with idiopathic generalized epilepsy.*

In the well-controlled trial supporting this indication, 22% of Keppra® patients achieved complete seizure freedom throughout the 12-week evaluation period compared with only 2% of placebo patients. With seizure freedom being the ultimate goal of epilepsy management Keppra® may be a valuable addition to the clinician's armamentarium."

This data supporting this new indication in Europe provides the first and only phase III, double-blind, randomized, placebo-controlled evidence on the safety and efficacy of an AED in patients with idiopathic generalized epilepsy experiencing myoclonic seizures. This data was reported at the 26th International Epilepsy Congress in Paris in August 2005.[6] The indication for Keppra® in the U.S. is still under review by the FDA.

About Keppra®

In Europe, Keppra® (levetiracetam) is indicated as adjunctive therapy in the treatment of partial onset seizures with or without secondary generalization in adults and children from 4 years of age with epilepsy and as adjunctive therapy in the treatment of myoclonic seizures in adults and adolescents from 12 years of age with Juvenile Myoclonic Epilepsy.[7] In Europe Keppra® is also indicated for intravenous administration and is available as 100mg/ml concentrate for solution for infusion. In the U.S., Keppra® is indicated as adjunctive therapy in the treatment of partial onset seizures in adults and children 4 years of age and older with epilepsy.[10] Keppra® is associated with the occurrence of central nervous system adverse events including somnolence and fatigue, behavioural abnormalities, as well as haematological abnormalities. In adults, Keppra® is also associated with co-ordination difficulties. In paediatric patients 4-16 years of age, the most common adverse events associated with Keppra® in combination with other AEDs were somnolence, accidental injury, hostility, nervousness and asthenia. In adults, the most common adverse events associated with Keppra® in combination with other AEDs were somnolence, asthenia, infection and dizziness. Please consult local prescribing information. 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 8,500 people in over 40 countries, UCB achieved revenue of 2.3 billion euro in 2005. UCB is listed on the Euronext Brussels Exchange with a market capitalisation of approximately 6.0 billion euro. Worldwide headquarters are located in Brussels, Belgium.

About Juvenile Myoclonic Epilepsy and Myoclonic Seizures

JME is classified as a type of idiopathic generalized epilepsy (IGE), in which seizures result from excessive electrical activity in the whole brain.[3] JME requires life-long treatment with anti-epileptic drugs.[1] Myoclonic seizures are short, jerky muscle spasms that can occur once or repetitively, on one or both sides of the body.[1]

References

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