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Press Release

FDA Approves Keppra® as Adjunctive Therapy in the Treatment of Myoclonic Seizures in Patients with Juvenile Myoclonic Epilepsy

Keppra® now approved to treat
a generalized seizure type in adult and adolescent patients

Brussels (Belgium) – August 23, 2006 – 5:30 PM CEST - Today UCB announced that the U.S. Food & Drug Administration (FDA) has approved the use of Keppra® (levetiracetam) as adjunctive therapy in the treatment of myoclonic seizures in adults and adolescents 12 years of age and older with juvenile myoclonic epilepsy (JME). Keppra® is widely prescribed as an add-on therapy in the treatment of partial onset seizures in adults and children four years of age and older with epilepsy. This new indication represents the first U.S. approval for Keppra® for the treatment of a generalized seizure type in epilepsy patients.

Commenting on the new U.S. approval Robert C. Knowlton, Associate Professor of Neurology, UAB Epilepsy Center, Birmingham, Alabama, U.S.A. said, *'Juvenile myoclonic epilepsy is an epilepsy syndrome that requires life-long treatment and it is paramount that therapy is both efficacious and well-tolerated in the long term. The trial supporting this new indication for Keppra® presents the first class 1 evidence on the efficacy and safety of an antiepileptic drug as add-on therapy in controlling myoclonic seizures in patients with juvenile myoclonic epilepsy and provides a welcome new treatment option for U.S. physicians and patients.'*

Juvenile myoclonic epilepsy 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 characterised by myoclonic jerks that occur in 100% of patients, with many also experiencing generalized tonic-clonic and absence seizures[2,3]. Juvenile myoclonic epilepsy is frequently misdiagnosed and this can lead to inappropriate treatment choices[1].

Key Clinical Trial Results

This clinical trial supporting this new indication for Keppra® provides the first and only phase III, double-blind, randomized, placebo-controlled evidence on the safety and efficacy of an antiepileptic drug as add-on therapy in patients with juvenile myoclonic epilepsy experiencing myoclonic seizures. Patients in this study included those with juvenile myoclonic epilepsy, juvenile absence epilepsy or with generalized tonic-clonic seizures on awakening. The majority were patients with juvenile myoclonic epilepsy.

Seizure frequency: The responder rate defined as ≥ 50% reduction in myoclonic seizure days during the treatment period *versus* baseline was 60.4% in the Keppra® group (n=54), compared with 23.7% in the placebo group (n=59) (*p=0.0001*)[4]

Seizure freedom: 15.1 % of Keppra® patients achieved freedom from myoclonic seizures during the treatment period compared with 3.4 % of placebo patients. [5]

Adverse events: The most common adverse events were somnolence (12% in the Keppra® group *versus* 2% in the placebo group), neck pain (8% in the Keppra® group *versus* 2% in the placebo group), and pharyngitis (7% in the Keppra® group *versus* 0% in the placebo group).[4]

About Keppra® in the USA[4]

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 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 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 antiepileptic drugs 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 antiepileptic drugs 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.

Please consult local prescribing information on Keppra® in Europe.

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 40 countries, UCB achieved revenue of 2.3 billion euro in 2005. UCB is listed on the Euronext Brussels Exchange.

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References

1. Renganathan R, Delanty N. Juvenile myoclonic epilepsy: under-appreciated and under-diagnosed. *Postgraduate Med J* 2003; 79: 78-80.
2. Duron RM, Medina MT, Martinez-Juarez IE, *et al.* Seizures of idiopathic generalized epilepsies. Epilepsia 2005;46 (supplement 9): 34-47.
3. Commission on Classification and Terminology of the International League Against Epilepsy. Proposal for revised classification of epilepsies and epileptic syndromes. *Epilepsia* 30:389-399, 1989. (Table 5, Table 6 and Glossary).
4. U.S. Keppra® Prescribing Information (www.Keppra.com)
5. UCB Data on File