

Press Release

Two European Regulatory Milestones for Keppra®

Approval for Intravenous Administration

Positive Opinion for Myoclonic Seizures in Juvenile Myoclonic Epilepsy

Brussels (BELGIUM) April 26, 2006 - Today UCB announced that the European Commission has approved the use of Keppra[®] (levetiracetam) 100 mg/mL concentrate for solution for intravenous infusion in the European Union for use as adjunctive therapy in the treatment of partial onset seizures with or without secondary generalisation in adults and children four years of age and older with epilepsy.

UCB also reported that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMEA) has adopted a positive opinion, recommending the approval of Keppra[®] as adjunctive therapy in the treatment of myoclonic seizures in adults and adolescents from 12 years of age with Juvenile Myoclonic Epilepsy (JME). The CHMP's opinion is now forwarded to the European Commission for review and final decision, which is expected within 90 days.

UCB's variation application with the EMEA is based on a phase III, double-blind, randomized, placebo-controlled study evaluating the efficacy and safety of Keppra® as adjunctive therapy in the treatment of myoclonic seizures in patients with idiopathic generalized epilepsy. The results of this study were presented at the 26th International Epilepsy Congress in Paris in August 2005.

'Keppra® is now the first and only newer anti-epileptic drug with both oral and intravenous formulations and we are pleased to provide European physicians and hospitals with an alternative for patients when oral administration is not feasible.' said Troy Cox, President CNS Operations, UCB. He added 'The positive opinion with respect to Keppra®'s expanded indication is also encouraging news for patients living with JME and myoclonic seizures, and we look forward to receiving a final determination from the European Commission.'

About Keppra®

In Europe, Keppra[®] (levetiracetam) is indicated 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 epilepsy¹. 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 epilepsy². Keppra[®] is associated with the occurrence of central nervous system adverse events including somnolence and fatigue, behavioural abnormalities, as well as hematological abnormalities. In adults, Keppra[®] is also associated with coordination difficulties. In pediatric 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.

References

- 1. SmPC (http://www.emea.eu.int/humandocs/Humans/EPAR/Keppra/Keppra/htm)
- 2. U.S. Full Prescribing Information (www.Keppra.com)

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