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Press Release

FDA Approves Keppra® Intravenous Formulation

Brussels (BELGIUM) August 2, 2006 – 7:00 am CET - Today UCB announced that the U.S. Food and Drug Administration (FDA) has approved Keppra® (levetiracetam) injection 500mg/5mL (100mg/mL) for use as adjunctive therapy in the treatment of partial-onset seizures in adults with epilepsy. Keppra® injection is an alternative for patients when oral administration is temporarily not feasible; it must be diluted prior to use and administered as a 15-minute intravenous infusion.

'*The addition of new intravenous formulations extend the treatment spectrum for patients with epilepsy allowing therapy to be individualized to particular clinical situations.'* said Orrin Devinsky, Professor of Neurology, Neurosurgery and Psychiatry, Comprehensive Epilepsy Center, New York University, US. He continued, *'The FDA approval of the intravenous formulation for Keppra® provides a welcome new option for U.S. physicians and patients.*'

Troy Cox, President CNS Operations, UCB said *'This U.S. approval closely follows the European approval of the IV formulation for Keppra® earlier this year. Keppra® is now the only newer anti-epileptic drug available in the U.S. and Europe with both oral and intravenous formulations.'*

In March 2006 the European Commission approved the use of Keppra® 100 mg/mL concentrate for solution for intravenous infusion 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.

About Keppra® in the US

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. Keppra® is associated with the occurrence of central nervous system adverse events including somnolence and fatigue, behavioral 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 anti-epileptic drugs (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.

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 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. Worldwide headquarters are located in Brussels, Belgium.

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Reference

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