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Press Release

A Key Regulatory Milestone for Keppra®

UCB Receives Positive Opinion for the Use of Keppra® as Monotherapy in Europe

Brussels, Belgium July 3, 2006: UCB today announced that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMEA) has issued a positive opinion to approve marketing authorisation of Keppra® (levetiracetam) 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.

According to Peter Verdru, M.D., Vice President, Clinical Research, Head of Neurology/Psychiatry Clinical Development, "This current filing highlights our commitment to patients with newly diagnosed epilepsy. UCB has undertaken a comprehensive clinical trial program for Keppra® and this positive news follows closely behind two recent European approvals for Keppra® – a new intravenous formulation, and a new indication as add-on therapy in the treatment of myoclonic seizures in Juvenile Myoclonic Epilepsy. We look forward to receiving the final determination of the European Commission and to making Keppra® available as a first-line treatment to epilepsy patients."

The submission is based on a well-controlled Phase III non-inferiority monotherapy trial comparing Keppra® with optimized use of controlled-release (CR) carbamazepine. Data from this trial demonstrated that Keppra® was non-inferior to CR-carbamazepine when used as monotherapy in the first-line treatment of adult patients with partial or generalised tonic-clonic seizures, and showed a more favourable tolerability profile[1]. In this trial Keppra® demonstrated six and twelve month seizure freedom rates of 73.0% and 56.6%, respectively when used as monotherapy in newly diagnosed patients[1].

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 epilepsy and as adjunctive therapy in the treatment of myoclonic seizures in adults and adolescents from 12 years of age with Juvenile Myoclonic Epilepsy. 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. 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 co-ordination 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 8,300 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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References

1. Ben-Menachem E, Brodie MJ, Perucca E. Efficacy of levetiracetam monotherapy; randomized double-blind head-to-head comparison with carbamazepine-CR in newly diagnosed epilepsy patients with partial onset or generalised tonic-clonic seizures [abstract]. Neurology 2006;65(5 Suppl 2):A73.