



UCB S.A. Allée de la Recherche 60, B-1070 Brussels (Belgium)

## ***Press Release***

### **Key Approval for Keppra<sup>®</sup> Offers New Treatment Option for Newly Diagnosed Epilepsy Patients**

#### **Keppra<sup>®</sup> Granted European Monotherapy Approval**

**Brussels, BELGIUM, August 18, 2006 – Time 07.00 CEST:** Newly diagnosed epilepsy patients in Europe with partial onset seizures can now benefit from first-line treatment with Keppra<sup>®</sup> (levetiracetam). This advance in epilepsy management follows the approval of Keppra<sup>®</sup> by the European Commission 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. The new indication is the latest in a series of new indications and formulation approvals, granted to UCB for Keppra<sup>®</sup> this year.

*'The monotherapy approval is a major milestone for Keppra<sup>®</sup> and for UCB. It reflects the wealth of clinical and scientific research that supports the expanding role of Keppra<sup>®</sup> in epilepsy management, and UCB in its commitment to improving the lives of epilepsy patients.'* said Troy Cox, President CNS Operations, UCB.

#### **Key Keppra<sup>®</sup> approvals for 2006**

**March 2006:** Keppra<sup>®</sup> becomes first newer anti-epileptic drug (AED) with both oral and intravenous (IV) formulations, when Keppra<sup>®</sup> Concentrate for solution for infusion receives EU approval for 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.

**April 2006:** Keppra<sup>®</sup> becomes the first newer AED approved in Europe for adjunctive therapy in the treatment of myoclonic seizures in adults and adolescents from 12 years of age with Juvenile Myoclonic Epilepsy (JME).

**August 2006:** Keppra® injection (intravenous formulation) receives U.S. approval for use as adjunctive therapy in the treatment of partial onset seizures in adults with epilepsy.

### **Notes to Editors**

The European approval of Keppra® monotherapy is supported by data from a pivotal positive controlled phase III clinical trial in new or recently diagnosed adult epilepsy patients with partial onset or generalised tonic-clonic seizures. Of the 472 patients who adhered to the treatment protocol, 73.0% of those who took Keppra® remained seizure-free for six months, and 56.6% for 12 months. This compared with 72.8% and 58.5% respectively in patients who took the current standard monotherapy – controlled release (CR) carbamazepine. In this study Keppra® was well tolerated with fewer patients taking Keppra® having an adverse event that meant they had to stop treatment or change their dosage, compared to carbamazepine CR<sup>1</sup>.

### **About Keppra® in Europe<sup>2</sup>**

Keppra® is indicated 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; 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 JME. In monotherapy the most commonly reported side effects were fatigue and somnolence. As adjunctive therapy in adults with partial onset seizures the most commonly reported side effects were somnolence, asthenia and dizziness. As adjunctive therapy in paediatric patients (4-16 years of age) with partial onset seizures the most commonly reported side effects were somnolence, hostility, nervousness, emotional lability, agitation, anorexia, asthenia and headache. In adults and adolescents with myoclonic seizures the most common reported side effects associated with Keppra® in combination with other AEDs were headache and somnolence. Keppra® is also indicated for intravenous administration and is available as 100mg/ml concentrate for solution for infusion. The most common adverse events from Keppra® intravenous use were dizziness, somnolence, headache and postural dizziness.

### **About Keppra® in the US<sup>3</sup>**

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 experiencing partial onset seizures, Keppra® is also associated with co-ordination 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 AEDs 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 AEDs were somnolence, asthenia, infection and dizziness. Keppra<sup>®</sup> is also available as an intravenous formulation for the adjunctive treatment of partial-onset seizures in adults with epilepsy. Keppra<sup>®</sup> injection is an alternative for patients when oral administration is temporarily not feasible. The adverse events that may result from Keppra<sup>®</sup> injection use include all those associated with Keppra<sup>®</sup> tablets and oral solution. For the U.S., prescribing information is available at [www.keppra.com](http://www.keppra.com).

### **About UCB**

UCB ([www.ucb-group.com](http://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.

### **Inquiries, please contact:**

Mareike Mohr

*Associate Director, Investor Relations*

Phone +32.2.559.9264

Email [mareike.mohr@ucb-group.com](mailto:mareike.mohr@ucb-group.com)

### **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.
2. Summary of Product Characteristics
3. U.S. Full Prescribing Information (available at [www.Keppra.com](http://www.Keppra.com))