Press Release - Regulated information

US FDA grants pediatric exclusivity for UCB's Keppra®

- **Period of exclusivity until January 2009 in the US**
- **Pediatric indication filed with FDA**

Brussels, BELGIUM – June 6, 2008 at 7:00 am CEST - UCB announced today that the US Food and Drug Administration (FDA) has granted pediatric exclusivity for Keppra® (levetiracetam). The decision was based on pediatric data submitted to the FDA following a written request in 2001. The Keppra® US '639 patent was set to expire in July 2008, however, this grant extends the period of exclusivity on Keppra® across all licensed indications by six months to January 2009.

UCB also announced today that the US FDA has accepted for filing and six-month priority review the supplementary New Drug Application (sNDA) for Keppra® as adjunctive treatment of partial onset seizures in infants and children with epilepsy, aged from one month to under four years.

"The FDA's filing acceptance and granting of priority review status reflects the need for new effective antiepileptic treatments for infants and children under four years," said Iris Loew-Friedrich, MD, PhD, Chief Medical Officer, UCB. "The trials supporting this sNDA included the third well-controlled trial of Keppra® in a pediatric population, with studies in partial onset seizures now extending from infants to children and adolescents."

The submission was based on multiple efficacy, safety and pharmacokinetic studies including data from a Phase III, double-blind, randomized, multi-centre, placebo-controlled study evaluating the efficacy and tolerability of levetiracetam oral solution (20-50 mg/kg/day) in 116 pediatric patients with refractory partial onset seizures, aged from one month to under four years. Prior to treatment, infants and children in this study were experiencing at least two partial onset seizures per week despite treatment with one or two other antiepileptic drugs.

Levetiracetam was shown to significantly reduce the frequency of partial onset seizures with 43.1% of levetiracetam-treated patients experiencing at least a 50% reduction in seizure frequency during the evaluation period (five days) compared with 19.6% of placebo-treated patients (p=0.013). Levetiracetam was generally well-tolerated in this pediatric population. The most commonly reported adverse events that occurred more frequently in the treatment group were somnolence (13.3% vs. 1.8% for placebo) and irritability (11.7% vs. 0 for placebo). The incidence of other adverse events was similar in both groups.

In October 2007, UCB announced that it had reached an agreement to settle pending patent infringement lawsuits in the US. Under the terms of the settlement agreement with Mylan, and subject to its receiving FDA approval, Mylan will be allowed to sell its generic levetiracetam tablets effective November 1, 2008, in advance of the expiry of UCB's market exclusivity on January 14, 2009.

About Epilepsy: Epilepsy is a chronic neurological disorder affecting 40 million people worldwide including 2.5 million people in the US. It is caused by abnormal, excessive electrical discharges of the nerve cells or neurons in the brain. Epilepsy is characterized by a tendency to have recurrent seizures and defined by two or more unprovoked seizures. There are many different seizure types and epileptic syndromes and effective classification guides treatment and prognosis. Between 70-80% of individuals are successfully treated with one of the more than 20 antiepileptic drugs now available. However, 20-30% of patients have either intractable or uncontrolled seizures or significant adverse side effects secondary to medication highlighting the ongoing need for the development of new antiepileptic drugs.

About Keppra® in the US: Keppra® (levetiracetam) tablets were first approved by the FDA in 1999 as adjunctive therapy in the treatment of partial onset seizures in adults with epilepsy. Since 1999, Keppra® has received several supplemental indications as adjunctive therapy for epilepsy.

Important Safety Information

Keppra® tablets and oral solution are indicated as adjunctive therapy in the treatment of partial onset seizures in adults and children 4 years of age and older with epilepsy, myoclonic seizures in adults and adolescents 12 years of age and older with juvenile myoclonic epilepsy, and primary generalized tonic-clonic seizures in adults and children 6 years of age and older with idiopathic generalized epilepsy. Keppra® injection is indicated as adjunctive therapy in the treatment of primary generalized tonic-clonic seizures in adults with idiopathic generalized epilepsy, myoclonic seizures in adults with juvenile myoclonic epilepsy and partial onset seizures in adults with epilepsy. Keppra® injection is an alternative for patients when oral administration is temporarily not feasible.

Keppra® tablets and oral solution are associated with the occurrence of central nervous system adverse events including somnolence and fatigue, behavioral abnormalities, as well as hematological abnormalities. In adults experiencing partial onset seizures, Keppra® is also associated with co-ordination difficulties. 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. 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 patients 12 years of age and older with juvenile myoclonic epilepsy, the most common adverse events associated with Keppra® in combination with other AEDs were somnolence, neck pain, and pharyngitis. In patients 6 years of age and older with idiopathic generalized epilepsy, the most common adverse event associated with Keppra® in combination with other AEDs was nasopharyngitis.

The adverse events that result from Keppra® injection use for primary generalized tonic-clonic seizures in adults with idiopathic generalized epilepsy, myoclonic seizures in adults with juvenile myoclonic epilepsy and partial onset seizures in adults with epilepsy include all of those associated with Keppra® tablets and oral solution.

US prescribing information is available at www.keppra.com or by calling 1-866-822-0068.

Further information

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About UCB

UCB, Brussels, Belgium (www.ucb-group.com) is a global leader in the biopharmaceutical industry 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 more than 10,000 people in over 40 countries, UCB achieved revenue of EURO 3.6 billion in 2007 on a pro forma basis. UCB S.A. is listed on the Euronext Brussels Exchange.

Forward looking statement

This press release contains forward-looking statements based on current plans, estimates and beliefs of management. Such statements are subject to risks and uncertainties that may cause actual results to be materially different from those that may be implied by such forward-looking statements contained in this press release. Important factors that could result in such differences include: changes in general economic, business and competitive conditions, effects of future judicial decisions, changes in regulation, exchange rate fluctuations and hiring and retention of its employees.