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Press Release

UCB Announces Positive Top-Line Phase III Results for Keppra® as Adjunctive Therapy for Partial Onset Seizures in Paediatric Patients from One Month to Less than Four Years of Age

Brussels, Belgium – April 20, 2007 at 7:00 AM CET – UCB today announced positive top-line results from a phase III, double-blind, randomized, multi-centre, placebo-controlled study evaluating the efficacy and tolerability of Keppra® (levetiracetam) *(20-50 mg/kg/day)* as adjunctive therapy in the treatment of partial onset seizures in children (*n=116*) from one month to less than four years of age. Compared with placebo, Keppra® was shown to significantly reduce the frequency of partial onset seizures in these paediatric patients with consistent results across all stratified age groups.

Commenting on the results, Jesús Eric Piña-Garza M.D., Professor of Paediatric Neurology & Director Pediatric Epilepsy Clinical Trials, Vanderbilt University, Nashville, Tennessee said *'There are very few studies assessing antiepileptic drug efficacy in infants. In this well-designed randomized trial Keppra® was shown to be more efficacious than placebo in controlling partial seizures in infants and young children with treatment resistant partial onset epilepsies. This study is a welcome addition to current information in paediatric epilepsy.'*

In this study 43.1% of Keppra®-treated patients experienced at least a 50% reduction in seizure frequency during the evaluaton period (five days) compared with 19.6% of placebo-treated patients. The most common treatment-emergent adverse events that occurred in Keppra®-treated patients and more frequently than placebo-treated patients were somnolence and irritability. Prior to treatment children in this study were experiencing at least two partial onset

seizures per week despite treatment with one or two other antiepileptic drugs. Efficacy assessment was based on 48 hour video EEG performed at baseline and at the end of the evaluation period with seizures identified and recorded by a central reader.

Fifty million people worldwide have epilepsy[2]. Childhood epilepsy is among the most prevalent neurological conditions. The effects of epilepsy on a child's psychological and social development are complex and cover all dimensions of a child's life and future.

Peter Verdru, Vice President, CNS Clinical Development, UCB said, '*This is the second double-blind, randomized, placebo-controlled trial of Keppra® in children, with studies in partial onset seizures now extending from infancy through adulthood.'* He continued*, 'This trial was designed and conducted in close collaboration with the regulatory authorities. On the basis of these positive results in younger patients with treatment resistant partial seizures we intend to file a supplementary new drug application for Keppra®'.*

About Keppra® in the US[3,4]

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, as adjunctive therapy in the treatment of myoclonic seizures in adults and adolescents 12 years of age and older with juvenile myoclonic epilepsy, and as adjunctive therapy in the treatment of primary generalized tonic-clonic seizures in adults and children 6 years of age and older with idiopathic generalized epilepsy (IGE). Keppra® tablets and oral solution are associated with the occurrence of central nervous system adverse events including somnolence and fatigue, co-ordination difficulties and behavioral abnormalities as well as hematological abnormalities. In adults experiencing partial onset seizures, the most common adverse events associated with Keppra® in combination with other antiepileptic drugs (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 antiepileptic drugs (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 experiencing primary generalized tonic-clonic seizures, the most common adverse event associated with Keppra® in combination with other AEDs was nasopharyngitis. 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 for partial onset seizures include all those associated with Keppra® tablets and oral solution. For the U.S., prescribing information is available at www.keppra.com.

About Keppra® in Europe[5]

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; as adjunctive therapy in the treatment of myoclonic seizures in adults and adolescents from 12 years of age with JME and as adjunctive therapy in the treatment of PGTC seizures in adults and adolescents from 12 years of age with IGE. In monotherapy the most commonly reported undesirable effects were fatigue and somnolence. As adjunctive therapy in adults with partial onset seizures the most commonly reported undesirable 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 undesirable effects were somnolence, hostility, nervousness, emotional lability, agitation, anorexia, asthenia and headache. In adults and adolescents with myoclonic seizures the most common reported undesirable effects associated with Keppra® in combination with other AEDs were headache and somnolence. In adults and adolescents with primary generalized tonic-clonic seizures the most common reported undesirable effects associated with Keppra® in combination with other AEDs was fatigue. Keppra® is also indicated for intravenous administration and is available as 100 mg/mL concentrate for solution for infusion. Undesirable effects that resulted from Keppra® intravenous use are similar to those associated with Keppra® oral use. Please consult local prescribing information.

About UCB

Headquartered in Brussels (Belgium), 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 more than 8400 people in over 40 countries, UCB achieved revenue of 2.5 billion euro in 2006. UCB is listed on the Euronext Brussels Exchange and owns 87.6% of Schwarz Pharma.

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References

1. UCB Data on File
2. Neurological Disorders: Public Health Challenges. *WHO Report* 1986
3. U.S. Prescribing Information Keppra® tablets and oral solution (24E) (available at www.Keppra.com).
4. U.S. Prescribing Information Keppra® injection (2E) (available at www.Keppra.com).
5. Keppra® Summary of Product Characteristics, January 2007 (available at www.emea.eu.int).