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Press Release

FDA Approves UCB's Keppra® for Use in Childhood Epilepsy

Brussels (Belgium), June 24, 2005 - UCB announced today that the U.S. Food and Drug Administration (FDA) has approved the company's anti-epilepsy drug Keppra® (levetiracetam) as add-on therapy in the treatment of partial-onset seizures in children four years of age and older with epilepsy. The FDA approved this new pediatric indication for Keppra® under priority review, a designation for products that address unmet medical needs and represent a significant improvement to therapies already available.

"More than 25% of children with epilepsy experience treatment resistant seizures or intolerable side effects from medication," said Tracy Glauser, M.D., director of the Comprehensive Epilepsy Program, Cincinnati Children's Hospital, and principal investigator of the well-controlled study reviewed for the pediatric indication. Dr. Glauser added that, "Keppra® was effective and well-tolerated by the children in the study, many of whom had failed on multiple anti-epileptic drugs (AEDs) prior to trying Keppra®."

"This approval provides another needed treatment option for children who suffer from epilepsy. We applaud the FDA making this therapeutic option available," said Eric Hargis, President of the Epilepsy Foundation in the US.

Clinical Trial Results

The approval of Keppra® (levetiracetam) for children in the U.S. was based on findings from one multi-center, randomized, double-blind, placebo-controlled pivotal study conducted at 60 sites in North America, in 198 children 4 to 16 years of age with partial onset seizures with or without secondary generalization uncontrolled by standard AEDs.[1,2] Study participants were taking one or

two other AEDs at entry. The study consisted of an 8-week baseline period and a 4-week titration period, followed by a 10-week evaluation period.

When measuring efficacy, those taking Keppra® had a significantly larger reduction (26.8%) in weekly seizure frequency over placebo, on average. Additionally, another measure of efficacy, responder rates (the portion of patients achieving a 50% or greater reduction in seizures) for patients taking Keppra were 44.6% *versus* 19.6% for placebo (both with a *p*=0.0002 compared to placebo).

"We are very pleased the FDA approved Keppra® for children, and look forward to making this therapy available to many of the 300,000 children in the U.S. with epilepsy," said Peter Verdru, M.D., Vice President Clinical Research and Head of Neurology, Psychiatry and Clinical Development, UCB Pharma, Inc.

In pediatric patients, 4 to 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.[2] Keppra® is associated with somnolence, fatigue, and behavioral abnormalities as well as hematological abnormalities.[3]

About Keppra® in the United States

In the U.S., Keppra® (levetiracetam) is approved for adjunctive therapy in the treatment of partial onset seizures in adults and children 4 years of age and older with epilepsy. Keppra® is available in 250, 500 and 750 mg tablets and a grape-flavored (100 mg/mL) oral solution for patients who prefer a solution or have difficulty swallowing tablets. Keppra® dosing must be individualized according to renal function status.[3] Since its launch, Keppra® has had more than 600,000 unique patient starts in the U.S.[4]

In adults, Keppra® use is associated with the occurrence of central nervous system adverse events, including somnolence and fatigue, coordination difficulties, and behavioral abnormalities as well as hematological abnormalities. In well-controlled adult clinical studies, the most frequently reported adverse events associated with the use of Keppra® in combination with other AEDs, not seen at an equivalent frequency among placebo-treated patients, were somnolence, asthenia, infection and dizziness.

Keppra® was approved in 1999 as adjunctive therapy for adults with partial onset seizures and is the most prescribed second-generation AED used in epilepsy in the U.S.[5] For full prescribing information please visit www.keppra.com.

About Keppra® in Europe

Keppra® was approved in Europe in 2000 as adjunctive therapy of partial onset seizures with or without secondary generalization for adults with partial onset seizures[6]. UCB submitted a new drug application to the EMEA for pediatric use and for an injectable formulation of Keppra® in March 2005 which are currently under review.

About UCB

UCB - www.ucb-group.com - is a global biopharmaceutical leader with headquarters in Brussels, Belgium, specialising in the fields of central nervous system disorders, allergy and respiratory diseases, immune and inflammatory disorders, as well as oncology. UCB key products are Keppra® (antiepileptic), Xyzal® and Zyrtec® (antiallergics), Nootropil® (cerebral function regulator), Tussionex™ (antitussive) and Metadate™ / Equasym XL™ (attention-deficit/hyperactivity disorder). UCB employs over 8,500 people operating in over 40 countries and achieved in 2004 revenues of € 2.1 billion (including net sales, royalties, and fees) and an operating profit before amortisation (EBITA) of € 389 million (on a pro-forma IFRS basis including 12 months of Celltech and excluding the Surface Specialties activities, divested in February 2005). UCB is listed on Euronext Brussels with a market capitalization of approximately € 5.5 billion.

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[1] Glauser TA, Gauer LJ, Chen L and LEV N159 Pediatric Study Group. Multicenter, double-blind, placebo-controlled trial of adjunctive levetiracetam (Keppra®) therapy (up to 60 mg/kg/day) in pediatric patients with refractory partial epilepsy. Epilepsia 2004; 45 (supplement 7): 186

[2] UCB Data on File

[3] Keppra® U.S. Package Insert

[4] NDCHealth Retail Pharmacy Database, May 2000 – April 2005

[5] IMS NDTI Drug Use, Rolling Quarter February – April 2005

[6] Keppra® Summary of Product Characteristics