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Press Release

European Commission Approves Use of UCB's Anti-Epileptic Keppra® as Adjunctive Therapy in Children Four Years of Age and Older with Partial-Onset Seizures

Brussels, BELGIUM - September 22, 2005 - Today UCB announced that the European Commission has approved the use of Keppra® (levetiracetam) in the European Union, as adjunctive therapy in the treatment of partial-onset seizures, with or without secondary generalisation, in children from four to sixteen years of age.

Approval was based on a pivotal paediatric clinical trial, the results of which were most recently* reported at the 6th European Paediatric Neurology Society Congress (14th-17th September 2005), in Sweden.¹ "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 study. "Keppra® was effective and well-tolerated by children in the study, many of whom had tried multiple anti-epileptic drugs prior to trying Keppra®."

In June 2005, the US Food and Drug Administration (FDA) approved the paediatric indication under priority review, a designation for products that address unmet medical needs and represent a significant improvement to products already available.

*** Note to Editors**

Results of this pivotal clinical trial were previously reported in the US at the 58th American Epilepsy Society Congress in December 2004².

References

1. Lu Z, Glauser TA, Ayala R, Elterman RD, Mitchell WG, Van Orman CB, Gauer LJ Levetiracetam adjunctive therapy in children with refractory partial epilepsy, in comparison with other new anti-epileptic drugs. Poster Presentation at the 6th European Paediatric Neurology Society Congress, Goteborg, September 2005.
2. Glauser TA, Gauer LJ, Chen L 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. Presentation at the 58th American Epilepsy Society Congress, New Orleans, 6 December 2004.

About Keppra®

In the US and Europe, Keppra® (levetiracetam) is indicated as adjunctive therapy in the treatment of partial onset seizures in adults and children four years of age and above with epilepsy. In adults, the use of Keppra® 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 paediatric patients 4 to 16 years of age, Keppra® is associated with somnolence, fatigue and behavioural abnormalities, as well as hematological abnormalities. In adults, the most common adverse events associated with Keppra® in combination with other AEDs are somnolence, asthenia, infection, and dizziness. Of these, most appeared to occur predominantly during the first 4 weeks of treatment. In pediatric patients 4 to 16 years of age, the most common adverse events associated with Keppra® in combination with other AEDs are somnolence, accidental injury, hostility, nervousness, and asthenia.

About UCB

UCB - www.ucb-group.com - is a global biopharmaceutical leader with headquarters in Brussels, Belgium, specializing 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™ CIII (antitussive) and Metadate CD™ CII / Equasym™ XL (attention-deficit/hyperactivity disorder). UCB employs over 8,500 people operating in over 40 countries. UCB is listed on Euronext Brussels.

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