FOR IMMEDIATE RELEASE

FDA grants priority review to levetiracetam for use in childhood epilepsy

Brussels, 17 February 2005: UCB Pharma Inc has been granted a priority review for the supplemental new drug application (sNDA) seeking approval of its leading anti-epilepsy drug (AED) Keppra®* (levetiracetam) as add-on therapy in children and adolescents with partial seizures in the USA.

Under a priority review, the Food and Drug Administration (FDA) sets a six month target for deciding whether to approve a new drug application, instead of the standard target of 10 months after the date the application is filed. A priority designation is intended for products that address unmet medical needs and, if approved, would be a significant improvement on products already on the market.

UCB Pharma Inc submitted the paediatric sNDA for Keppra® on 20 December 2004 requesting approval of Keppra® for the adjunctive treatment of partial seizures in children down to four years of age. Keppra® was first marketed in the year 2000 and is now the most prescribed second generation AED for adults with partial onset seizures in the USA.[1] The introduction of Keppra for children, as early as Q3 2005 in the US and EU, will give even more patients the opportunity to receive this innovative medicine.

The application is based on recent pivotal trial results in 198 patients showing excellent efficacy and safety in children aged 4-16 years with refractory epilepsy.[2] The children who took part in the study were taking one or two other AEDs at entry.[2] Seven percent of children who took Keppra® became seizure free during the 14 week double-blind, placebo controlled treatment period, compared with 1% of those taking placebo. Responder rates – a 50% or greater reduction in seizures – were 45% on Keppra® treatment and 20% on placebo (p=0.0002).[2]

Dr Tracy Glauser, Director Comprehensive Epilepsy Program, Cincinnati Children's Hospital, and principal investigator of the study stressed the importance of early, aggressive treatment of childhood seizures to lessen the risk of injury to the child, maximize school performance, and thereby improve their quality of life.

'Keppra® was effective and well tolerated by the children in our study, many of whom had been on eight or nine different drugs before trying Keppra®. These positive results, in such a severe population, suggest we could see even better results in less severely ill children,' he said.

The recent identification of SV2A as a binding site for levetiracetam confirms that Keppra® possesses a mechanism of action that is truly distinct from that of all other AEDs.[3].

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* Keppra® is a registered trademark of the UCB Group

About UCB Pharma

UCB Pharma is part of the UCB Group, a global pharmaceutical and specialty chemical company with headquarters in Brussels, Belgium. UCB is listed on Euronext Brussels and achieved, in 2004, sales of €3,068 million and a net profit of €362 million. UCB Pharma is a global biopharma leader, specialising in the fields of central nervous system disorders, allergy and respiratory disease, immune and inflammatory disorders and oncology. UCB Pharma's key products are *Keppra*® (antiepileptic), *Xyzal*® and *Zyrtec*®† (antiallergics), *Nootropil*® (cerebral function regulator), and *Tussionex*® (antitussive). UCB Pharma employs over 8,300 people operating in over 100 countries and in 2004 achieved sales of € 1,679 million.

†Zyrtec® is licensed to, and co-promoted with, Pfizer in the US.

References

1. Available from: IMS Health, National Disease and Therapeutic Index™. Accessed Oct 2004: Based on an intent-to-treat (ITT) analysis; when generalised seizures were specified, the data were excluded from this analysis.

2. 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 (B.03)

3. Lynch BA, Lambeng N, Nocka K et al. The synaptic vesicle protein SV2A is the binding site for the antiepileptic drug levetiracetam. *PNAS* 2004; 101 (26): 9861-9866

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