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Press Release

New Data on the Use of Keppra® (levetiracetam) as Adjunctive Treatment in Idiopathic Generalised Epilepsy Patients with Primary Generalised Tonic-Clonic Seizures

Brussels, 6 December 2005: According to new data, presented at a UCB sponsored Scientific Exhibit at the 59th Annual Meeting of the American Epilepsy Society in Washington, DC, U.S., approximately one in four patients with poorly controlled idiopathic generalised epilepsy (IGE) having primary generalised tonic-clonic (PGTC) seizures became free from all types of seizures when Keppra® (levetiracetam) was administered as an add-on treatment during a 20 week evaluation period. In comparison, only one in twelve of those who took a placebo in addition to their usual therapy became seizure free.

Study investigator, Dr Robert Leroy, from the Neurological Clinic of Texas, commented, "These are major seizures which disrupt the working, school and social lives of those who have them. The results show that Keppra® significantly reduced PGTC seizures. The tolerability profile is comparable to that seen in studies of Keppra® in patients with epilepsy and other types of seizures."

All of the 164 patients aged 4 to 65 years enrolled in the trial had at least three PGTC seizures during the eight weeks prior to treatment, despite taking one or two anti-epileptic drugs (AEDs). After a four-week prospective baseline period, the patients were randomised to either Keppra®, up-titrated to 3000 mg/day in adults or a target dose of 60 mg/kg/day in children, or placebo, followed by a 20 week stable dose period.

Treatment with Keppra® reduced the weekly PGTC seizure frequency significantly more than placebo (*p=0.004*). In the Keppra® group, 72.2 % of patients had at least a 50% reduction from combined baseline in PGTC seizure frequency per week during the treatment period, compared with 45.2 % in the placebo group (*p=0.0005*). During the 20-week evaluation period 24.1 % of patients treated with Keppra® became free from all types of seizures compared with only 8.3% of placebo-treated patients (*p=0.009*).

A preliminary assessment of safety data showed similar findings to the established safety profile of Keppra®.

Notes to Editors

1. In a press release on October 26, 2005, UCB announced top-line positive clinical trial results on this study evaluating Keppra® (levetiracetam) as adjunctive treatment in adult and paediatric patients (4-65 years of age) suffering from IGE with PGTC seizures.

2. Idiopathic generalised epilepsies (IGE) are a range of generalised epilepsies for which there is no obvious cause, other than an inherited (genetic) predisposition. They are characterised by generalised tonic-clonic, myoclonic and absence seizures. Myoclonic seizures are short, jerky muscle spasms that can occur singly or repetitively, on one or both sides of the body. In a previous study, Keppra® was shown to be highly effective as an adjunctive therapy in IGE with myoclonic seizures, with 58.3% of patients (age 12-65 years) achieving a reduction in myoclonic seizure days of at least 50% compared with 23.3% in the placebo group (*p=0.0002*) T[1].

   UCB recently filed a variation application with the European Medicines Agency (EMEA) and a supplemental new drug application (sNDA) with the U.S. Food and Drug Administration (FDA) for the use of Keppra® as adjunctive therapy in the treatment of myoclonic seizures in patients, 12 years of age and older with juvenile myoclonic epilepsy.

References

[1] Verdru, P., Wajgt, A., Schiemann Delgado J., Noachtar, S. Efficacy and safety of levetiracetam 3000 mg/d as adjunctive treatment in adolescents and adults suffering from idiopathic generalised epilepsy with myoclonic seizures. Presented at the 26th International Epilepsy Congress, Paris, August 2005

About Keppra®

In the U.S. and Europe, Keppra® (levetiracetam) is indicated as adjunctive therapy in the treatment of partial onset seizures in adults and children 4 years of age and older 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 paediatric patients the most common adverse events associated with Keppra® in combination with other AEDs are somnolence, accidental injury, hostility, nervousness, and asthenia.

For full U.S. prescribing information for Keppra® please visit Hwww.keppra.com

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, inflammatory diseases, and 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. UCB is listed on Euronext Brussels (UCB / UCBBt.BR / UCB BB).

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