

Press Release

UCB Reports Positive Clinical Trial Results for Keppra[®] as Adjunctive Therapy in the Treatment of Primary Generalised Tonic-Clonic Seizures

Brussels (Belgium) October 27, 2005: UCB today announced positive clinical trial results from a study evaluating Keppra[®] (levetiracetam) as adjunctive treatment in adult and paediatric patients (4-65 years of age) suffering from idiopathic generalised epilepsy (IGE), with primary generalised tonic-clonic (PGTC) seizures.

The results of this phase III, double-blind, multicentre, randomised, placebo-controlled study in 164 patients demonstrated that Keppra[®] significantly reduced the frequency of PGTC seizures when compared with placebo. Seizures were previously uncontrolled despite treatment with one or two concomitant anti-epileptic drugs.

"Tonic-clonic seizures are the most debilitating seizure type within the generalised epilepsies." said Dr. Robert Leroy, Neurological Institute of Texas. "Historically referred to as 'grand mal', these seizures can have a significant negative impact on quality of life. Epidemiological studies¹ indicate that generalised tonic-clonic seizures are common. Their incidence is almost one in four (23%) of all cases of epilepsy."

¹ Hauser, W.A., Annegers, J.F. & Kurland, L.T. (1993) Incidence of Epilepsy and Unprovoked Seizures in Rochester, Minnesota: 1935-1984 *Epilepsia*, 34 (3), 453-468

According to Peter Verdru, MD, Vice-President Clinical Research, Head of Neurology/Psychiatry Clinical Development, UCB, "The positive clinical trial results in generalised tonic-clonic seizures represent a further milestone in the development of Keppra[®]. These results add to the clinical trial data with Keppra[®] as an adjunctive therapy in myoclonic seizures, as well as, its established profile as an adjunctive treatment in partial seizures."

Regulatory Filings Submitted to FDA and EMEA for Keppra[®] as AdjunctiveTreatment for Myoclonic Seizures in Juvenile Myoclonic Epilepsy

UCB also announced that it has 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. This application for a new indication is based on a phase III, double-blind, randomized, placebo-controlled study evaluating the efficacy and safety of Keppra[®] as adjunctive therapy in the treatment of myoclonic seizures in patients with idiopathic generalized epilepsy. Positive results of this study were presented at the 26th International Epilepsy Congress in Paris in August 2005.

Notes to Editors

About Myoclonic Seizures and Juvenile Myoclonic Epilepsy

Myoclonic seizures are short, jerky muscle spasms that can occur singly or repetitively on one or both side of the body. They occur in a variety of epilepsy syndromes that have different characteristics. Myoclonic seizures are the hallmark symptom of Juvenile Myoclonic Epilepsy (JME). JME is classified as a type of idiopathic generalised epilepsy (IGE). In IGE seizures result from excessive electrical activity in the whole brain. JME requires lifelong treatment with anti-epileptic drugs (AEDs) and accounts for about 10% of all cases of epilepsy.

About Generalised Tonic-Clonic Seizures

Generalised tonic-clonic seizures begin with a sudden loss of consciousness and stiffening of the muscles, followed by rapid rhythmic jerking of the arms and legs. Other symptoms such as a change in heart rate and blood pressure, increased production of saliva and an increase in bladder pressure that often causes incontinence can also occur.

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 with epilepsy, aged four years and above. 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, 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. UCB is listed on Euronext Brussels (UCB / UCBBt.BR / UCB BB).

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