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Press Release

UCB's Anti-Epilectic Keppra®
Meets Primary End-Point in Monotherapy Trial

Brussels, BELGIUM September 15th, 2005: UCB today announced that the primary end-point from its pivotal Phase III monotherapy clinical trial had been met. This trial compared Keppra® (levetiracetam) to sustained release carbamazepine in newly diagnosed patients, suffering from epilepsy with partial or generalised tonic-clonic seizures. Keppra® demonstrated non-inferiority* to carbamazepine on seizure freedom[1]. In addition the trial provided further evidence of Keppra®'s favourable tolerability.

"*Keppra® emerged from this study as the first of the new generation anti-epileptic drugs to show non-inferiority to sustained release carbamazepine with six month seizure freedom rates** of 73.0% and 72.8% for the Keppra® and carbamazepine groups, respectively"* said Professor Emilio Perucca, Lead Trial Investigator, University of Pavia, Italy. *"The trial represents the first randomized, double-blind, positive controlled epilepsy monotherapy study to both reflect clinical practice and meet the most recent regulatory requirements, ensuring optimal*** use of the current standard comparator, carbamazepine."*

This monotherapy trial represents the first study to follow the European Medicines Agency's (EMEA) Committee for Medicinal Products for Human Use (CHMP) Note for Guidance on the Clinical Investigation of Medicinal Products in the Treatment of Epileptic Disorders.

Roch Doliveux, CEO, UCB concluded "*With Keppra® and its epilepsy franchise, UCB is committed to supporting patients and their treating physicians in achieving the ultimate goal of epilepsy management, that is, complete freedom from seizures with minimal side effects.*"

UCB plans to file a marketing authorisation application with the EMEA for the use of Keppra® as monotherapy in patients with epilepsy and also plans to review the data with the US Food and Drug Administration (FDA).

References

1. UCB Data on File

Note to Editors

*Non-inferiority

The EMEA's CHMP requires demonstrating at least a similar benefit/risk balance of a test product as compared to an acknowledged standard product at its optimal use, through the conduct of a randomised, double-blind, non-inferiority trial.

**Seizure freedom rates

- Six month seizure freedom rates of 73.0% and 72.8% for Keppra® and carbamazepine sustained release, respectively were achieved from the per-protocol population, i.e. a subset of the intention-to-treat population excluding patients with protocol deviations
- Six month seizure freedom rates of 66.7% for both Keppra® and carbamazepine sustained release were achieved from the intention-to-treat population, i.e. patients randomised who took at least one dose of the study drug

***Optimal use of the comparator implies:

- patients with primary generalised seizures were excluded from the trial
- a low-initial target dose and a slow titration regimen were applied
- carbamazepine's sustained release formulation was used.

About Keppra®

In Europe, Keppra® is approved as adjunctive therapy in the treatment of partial onset seizures with or without secondary generalisation, in patients over 16 years of age. In August 2005, the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMEA) issued a positive opinion, recommending approval of Keppra® as adjunctive therapy in the treatment of partial-onset seizures, with or without secondary generalisation, in children four years of age and older with epilepsy. This positive opinion is currently under consideration by the European Commission.

In the US, Keppra® is indicated as adjunctive therapy in the treatment of partial onset seizures in adults and children four years of age and older with epilepsy. 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 adults, the most common adverse events associated with Keppra® in combination with other AEDs were somnolence, asthenia, infection, and dizziness.

In pediatric patients 4 to 16 years of age, Keppra® is associated with somnolence, fatigue, and behavioral abnormalities, as well as hematological abnormalities. Of these most appeared to occur predominantly during the first 4 weeks of treatment. In pediatric patients 4 to16 years of age, the most common adverse events associated with Keppra® in combination with other AEDs were 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™ (antitussive) and Metadate CD™ / 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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