



Keppra XR™ approved in the U.S.

- As adjunctive therapy, Keppra XR™ offers significant partial onset seizure reduction, proven tolerability, and once-daily dosing
- Keppra XR™ is built on a trusted heritage

Brussels, BELGIUM – September 15, 2008 at 7:00 am CEST – press release,
regulated information: UCB announced today that the U.S. Food and Drug Administration (FDA) has approved Keppra XR™ (*levetiracetam* extended-release tablets) for use as an add-on to other antiepileptic treatments for people with partial onset seizures who are 16 years of age and older. Keppra XR™ is expected to be available in U.S. pharmacies at the end of September 2008.

The goal of therapy with antiepileptic drugs (AEDs) is freedom from seizures and minimal side effects. While many people with epilepsy are successfully treated with one or more of the currently available AEDs, a significant percentage still live with uncontrolled seizures or intolerable side effects.

"With solid clinical trial data supporting Keppra XR™ efficacy and tolerability, this once-daily antiepileptic drug can play an important role in treating people with epilepsy," said lead investigator Dr. Jukka Peltola, Department of Neurology, Tampere University Hospital, Finland. "We found in the clinical trial that Keppra XR™ provided significant partial onset seizure control in once-daily dosing when added to other antiepileptic drugs and that it was generally well-tolerated."

Building On A Trusted Heritage

"This is one of many milestones at UCB to develop new treatment options for people with epilepsy," said Troy Cox, Senior Vice President UCB & President CNS Operations.

"Keppra XR™ provides a way to simplify treatment and offers another chance to achieve seizure control, which is an important goal for patients living with epilepsy."

The immediate release tablet form of Keppra® (*levetiracetam*) was first approved by the FDA in 1999 as adjunctive therapy in the treatment of partial onset seizures in adults with epilepsy. Since then, Keppra® has become a leading antiepileptic drug in the U.S.

Important Safety Information

Keppra XR™ extended release tablets are indicated as adjunctive therapy in the treatment of partial onset seizures in patients 16 years of age and older with epilepsy.

Keppra XR™ causes somnolence, dizziness, and behavioural abnormalities. The most common adverse reactions observed with Keppra XR™ combination with other AEDs were somnolence and irritability.

The adverse reactions that may be seen in patients receiving Keppra XR™ are expected to be similar to those seen in patients receiving immediate-release Keppra® tablets.



Kepra® immediate-release tablets cause somnolence and fatigue, coordination difficulties, and behavioural abnormalities (e.g., psychotic symptoms, suicidal ideation, and other abnormalities) as well as hematological abnormalities. In adults experiencing partial onset seizures, the most common adverse reactions observed with Kepra® in combination with other AEDs were somnolence, asthenia, infection and dizziness.

Kepra XR™ should be gradually withdrawn to minimize the potential of increased seizure frequency.

Dosing must be individualized according to the patient's renal function state. The dosage should be reduced in patients with impaired renal function receiving Kepra XR™. In patients with end stage renal disease on dialysis, it is recommended that immediate-release Kepra® be used instead of Kepra XR™.

For full prescribing information, please see www.KepraXR.com.

In order to ensure patient access to this valuable medication in the U.S., UCB is initiating a co-pay support program. For more information, contact the U.S. UCB Medical Information at 1-866-822-0068 (press 9).

About Epilepsy

Epilepsy is a chronic neurological disorder affecting approximately three million people in the U.S.—making it more common than multiple sclerosis and Parkinson's disease combined. It is caused by abnormal, excessive electrical discharges of the nerve cells, or neurons, in the brain. Epilepsy is characterized by a tendency to have recurrent seizures and defined by two or more unprovoked seizures. There are many different seizure types and epileptic syndromes. 40 % of patients taking only one AED continue to experience seizures, and approximately 30% of patients taking adjunctive therapy continue to experience seizures. This highlights the ongoing need for the development of new AEDs. For more information about epilepsy, visit www.epilepsyfoundation.org, www.epilepsy.com, or www.epilepsyadvocate.com.

Further information

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About UCB

UCB, Brussels, Belgium (www.ucb-group.com) is a global leader in the biopharmaceutical industry dedicated to the research, development and commercialisation of innovative medicines with a focus on the fields of central nervous system and immunology disorders. Employing around 12 000 people in over 40 countries, UCB achieved revenue of 3.6 billion euro in 2007. UCB is listed on Euronext Brussels (symbol: UCB).

Forward looking statement

This press release contains forward-looking statements based on current plans, estimates and beliefs of management. Such statements are subject to risks and uncertainties that may cause actual results to be materially different from those that may be implied by such forward-looking statements contained in this press release. Important factors that could result in such differences include: changes in general economic, business and competitive conditions, effects of future judicial decisions, changes in regulation, exchange rate fluctuations and hiring and retention of employees.