



UCB Announces FDA Approval for Keppra® in Infants and Children from One Month of Age with Partial Onset Seizures

- FDA expands indication for Keppra® as adjunctive therapy for partial onset seizures to include children from one month of age
- Clinical development program in young children reinforces UCB's long-term commitment to improving the lives of people with epilepsy

Atlanta – January 25, 2012 - UCB announced today that the U.S. Food and Drug Administration (FDA) has approved Keppra® (levetiracetam) tablets and oral solution as adjunctive therapy in the treatment of partial onset seizures in adults and children one month of age and older with epilepsy. Keppra® was previously approved in the U.S. as adjunctive therapy for partial onset seizures in adults and children four years of age and older with epilepsy.

"As a leader in epilepsy, UCB has a responsibility to develop effective medicines that address unmet medical needs," said Professor Dr. Iris Loew-Friedrich, Chief Medical Officer and Executive Vice President UCB. "Our continuing development program with Keppra® in young children demonstrates our long-term commitment to epilepsy."

The approval was based on data from a Phase III, double-blind, randomized, multi-center, placebo-controlled study evaluating the efficacy and tolerability of Keppra® oral solution (20-50 mg/kg/day) in 116 pediatric patients with refractory partial onset seizures, aged from one month to under four years. Keppra® was shown to significantly reduce the frequency of partial onset seizures with 43.1% of Keppra®-treated patients experiencing at least a 50% reduction in seizure frequency during the evaluation period (five days) compared with 19.6% of placebo-treated patients ($p=0.013$). Keppra® was generally well-tolerated in this pediatric population. The most commonly reported adverse events that occurred more frequently in the treatment group were somnolence (13.3% vs. 1.8% for placebo) and irritability (11.7% vs. 0% for placebo).¹

In 2009, the European Commission granted marketing authorisation for Keppra® in the European Union as adjunctive treatment of partial-onset seizures in infants and young children aged one month to under four years. Keppra® has provided the foundation for UCB's growing epilepsy franchise which has been extended to include Vimpat® (lacosamide) which is marketed in the European Union as adjunctive therapy for the treatment of partial onset seizures with or without secondary generalization in patients with epilepsy, aged 16 years and older and in the U.S. as adjunctive therapy in the treatment of partial onset seizures in patients with epilepsy, aged 17 years and older. In the U.S. Vimpat® is a Schedule V controlled substance.



About Keppra® in the U.S.

In the U.S. Keppra® tablets and oral solution are indicated as adjunctive therapy in the treatment of partial onset seizures in adults and children one month of age and older with epilepsy, myoclonic seizures in adults and adolescents 12 years of age and older with juvenile myoclonic epilepsy, and primary generalized tonic-clonic seizures in adults and children 6 years of age and older with idiopathic generalized epilepsy. Keppra® injection is indicated as adjunctive therapy in the treatment of primary generalized tonic-clonic seizures in adults (≥16 years of age) with idiopathic generalized epilepsy, myoclonic seizures in adults with juvenile myoclonic epilepsy and partial onset seizures in adults with epilepsy. Keppra® injection is an alternative for patients when oral administration is temporarily not feasible.

Keppra® in the U.S. - Important Safety Information

Antiepileptic drugs (AEDs) increase the risk of suicidal thoughts or behavior in patients taking these drugs for any indication. Patients treated with any AED for any indication should be monitored for the emergence or worsening of depression, suicidal thoughts or behavior, and/or any unusual changes in mood or behavior. Keppra® is also associated with the occurrence of central nervous system adverse events including somnolence and fatigue and behavioral abnormalities (e.g., psychotic symptoms, suicidal ideation and other abnormalities). Keppra® should be gradually withdrawn to minimize the potential of increased seizure frequency. In adults experiencing partial onset seizures, the most common adverse events associated with Keppra® in combination with other AEDs were somnolence, asthenia, infection and dizziness. In pediatric patients, the most common adverse events associated with Keppra® in combination with other AEDs were fatigue, aggression, nasal congestion, decreased appetite, and irritability. The adverse reactions for patients with JME and PGTC seizures are expected to be essentially the same as for patients with partial seizures. The adverse reactions for Keppra® injection include all of those associated with Keppra® tablets and oral solution. US prescribing information is available at

http://www.ucb.com/up/ucb_com_products/documents/Keppra_Labeling_12_2011.pdf
http://www.ucb.com/up/ucb_com_products/documents/Keppra_%20Injection_COL_%208E_%202006_2011.pdf

About Vimpat® in the U.S.

In the U.S. Vimpat® tablets and injection were launched in May 2009 as an add-on therapy for the treatment of partial onset seizures in people with epilepsy who are aged 17 years and older. Vimpat® injection is a short-term replacement when oral administration is not feasible in these patients. Vimpat® oral solution was launched in June 2010.

Vimpat® in the U.S. - Important Safety Information

AEDs increase the risk of suicidal behavior and ideation. Patients taking Vimpat® should be monitored for the emergence or worsening of depression, suicidal thoughts or behavior, and/or any unusual changes in mood or behavior. The most common adverse reactions occurring in ≥10 percent of Vimpat®-treated patients, and greater than placebo, were dizziness, headache, nausea, and diplopia. For full prescribing information on Vimpat®, visit <http://www.vimpat.com/prescribing-information.aspx> (Accessed 18th October, 2011).

For more information on Vimpat®, visit www.Vimpat.com or contact UCB at (800) 477-7877. Vimpat® (C-V) is a Schedule V controlled substance.



Reference

Pina Garza, E-G et al. (2009) Adjunctive levetiracetam in infants and young children with refractory partial-onset seizures Epilepsia, 50(5):1141-1149

For further information

*Kristie Madara, U.S. Corporate Communications, UCB
T + 1 (770) 970-8726, kristie.madara@ucb.com*

*France Nivelles, Global Communications, UCB
T +32.2.559.9178, france.nivelles@ucb.com*

*Eimear O'Brien, Director, Brand Communications, UCB
T +32.2.559.9271, eimear.obrien@ucb.com*

*Antje Witte, Investor Relations UCB
T +32.2.559.9414, antje.witte@ucb.com*

About UCB

UCB, Brussels, Belgium (www.ucb.com) is a global biopharmaceutical company focused on the discovery and development of innovative medicines and solutions to transform the lives of people living with severe diseases of the immune system or of the central nervous system. With more than 8,500 people in about 40 countries, the company generated revenue of EUR 3.2 billion in 2010. UCB is listed on Euronext Brussels (symbol: UCB).

Forward looking statements

This press release contains forward-looking statements based on current plans, estimates and beliefs of management. All statements, other than statements of historical fact, are statements that could be deemed forward-looking statements, including estimates of revenues, operating margins, capital expenditures, cash, other financial information, expected legal, political, regulatory or clinical results and other such estimates and results. By their nature, such forward-looking statements are not guarantees of future performance and are subject to risks, uncertainties and assumptions which could cause actual results to differ materially 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, the inability to obtain necessary regulatory approvals or to obtain them on acceptable terms, costs associated with research and development, changes in the prospects for products in the pipeline or under development by UCB, effects of future judicial decisions or governmental investigations, product liability claims, challenges to patent protection for products or product candidates, changes in laws or regulations, exchange rate fluctuations, changes or uncertainties in tax laws or the administration of such laws and hiring and retention of its employees. UCB is providing this information as of the date of this press release and expressly disclaims any duty to update any information contained in this press release, either to confirm the actual results or to report a change in its expectations.

###