



Keppra XR™ Extended- Release Tablets Filed with the FDA

U.S. Food and Drug Administration (FDA) has accepted for filing the New Drug Application (NDA) for the use of Keppra XR™ (levetiracetam) in the adjunctive treatment of partial onset seizures in adults with epilepsy.

Brussels, BELGIUM – January 16, 2008 at 7:00 am CET – UCB announced today that the New Drug Application (NDA) for the use of Keppra XR™ (levetiracetam) extended- release tablets in the adjunctive treatment of partial onset seizures in adults with epilepsy has been accepted for filing by the U.S. Food and Drug Administration (FDA).

“This filing is another important step in the development of UCB's epilepsy franchise and demonstrates our commitment to bringing new and innovative therapies to the epilepsy community.” said Iris Loew-Friedrich, MD, PhD, Global Head of Development, UCB Group. “There is an ongoing need for new antiepileptic drug options without the limitations of twice daily dosing. Epilepsy therapies with more convenient dosing schedules may help encourage greater patient compliance, which is important to effective seizure control.”

The filing for Keppra XR™ is supported by a Phase III, multicenter, randomized, double-blind, placebo-controlled study evaluating the efficacy, safety, and tolerability of extended-release levetiracetam tablets (2x500 mg) once-daily as adjunctive therapy in 158 refractory epilepsy patients, 12 to 70 years of age, with partial onset seizures.¹

The study met its primary endpoint for seizure reduction over placebo during the treatment period ($p=0.038$). The median per cent reduction of partial onset seizures in the extended-release levetiracetam group was 46.1% compared to 33.4% with placebo during the 12 week treatment period. Additionally, 24.0% of patients randomized to the extended-release levetiracetam group had seizure frequency per week reduced by 75-100%, compared with 11.4% of patients in the placebo group. In the extended-release levetiracetam group 10.1% of patients had 100% reduction in partial onset seizures and 8.9% were free from any type of seizure over the treatment period, compared to 2.5% and 1.3% in the placebo group, respectively.¹

The study also found that extended-release levetiracetam tablets were generally well tolerated. The most common reported adverse events that occurred more frequently in the extended-release levetiracetam group were somnolence, influenza, nausea, nasopharyngitis, irritability, and dizziness.¹



About Epilepsy^{2,3,4,5}: Epilepsy is a chronic neurological disorder affecting 40 million people worldwide including 2.5 million people in the US. 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 and effective classification guides treatment and prognosis. Between 70-80% of individuals are successfully treated with one of the more than 20 antiepileptic drugs now available. However, 20-30% of patients have either intractable or uncontrolled seizures or significant adverse side effects secondary to medication highlighting the ongoing need for the development of new antiepileptic drugs.

About Keppra® in the U.S.: Keppra® (levetiracetam) tablets were first approved by the FDA in 1999 as adjunctive therapy in the treatment of partial onset seizures in adults with epilepsy. Since 1999, Keppra® has received several supplemental indications as adjunctive therapy for epilepsy, making it one of the few treatments approved to treat seizure types that together account for more than 80 percent of all seizures.⁶

Important Safety Information^{7,8}

Keppra® tablets and oral solution are indicated as adjunctive therapy in the treatment of partial onset seizures in adults and children 4 years 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 myoclonic seizures in 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® tablets and oral solution are associated with the occurrence of central nervous system adverse events including somnolence and fatigue, behavioral abnormalities, as well as hematological abnormalities. In adults experiencing partial onset seizures, Keppra® is also associated with co-ordination difficulties. 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 4-16 years of age experiencing partial onset seizures, the most common adverse events associated with Keppra® in combination with other AEDs were somnolence, accidental injury, hostility, nervousness and asthenia. In patients 12 years of age and older with juvenile myoclonic epilepsy, the most common adverse events associated with Keppra® in combination with other AEDs were somnolence, neck pain, and pharyngitis. In patients 6 years of age and older with idiopathic generalized epilepsy, the most common adverse event associated with Keppra® in combination with other AEDs was nasopharyngitis.

The adverse events that result from Keppra® injection use for myoclonic seizures in juvenile myoclonic epilepsy and partial onset seizures in adults include all of those associated with Keppra® tablets and oral solution.

U.S. Prescribing information is available at www.keppra.com or by calling 1-866-822-0068.

References

1. *A double-blind, placebo-controlled, randomized efficacy and safety study of levetiracetam extended release formulation (LEV XR), administered as 2x500 mg LEV XR tablets once daily as add-on therapy in subjects from 12 to 70 years with refractory epilepsy suffering from partial onset seizures. NO1235 Study. UCB, Inc. Data on File. 2007.*
2. *Epilepsy Foundation. Epilepsy and Seizure Statistics. Available at: <http://www.epilepsyfoundation.org/about/>. Accessed on October 29, 2007.*
3. *French JA, Kanner AM, Bautista J et al. Efficacy and tolerability of the new antiepileptic drugs II: treatment of refractory epilepsy: report of the Therapeutics and Technology Assessment Subcommittee and Quality Standards Subcommittee of the American Academy of Neurology and the American Epilepsy Society. Neurology 2004; 62, 1261-1273*
4. *European White Paper on Epilepsy, EUCARE 2001*



5. http://www.who.int/whr/1997/media_centre/50facts/en/index.html (Accessed October 9th 2007)
6. Hauser W, Annegers J, Rocca W et al. *Descriptive epidemiology of epilepsy: contribution of population based studies from Rochester, Minnesota. Mayo Clinic Proceedings; 1996: 71:576-586.*
7. U.S. Prescribing Information oral dose forms (24E) (available at www.Keppra.com)
8. U.S. Prescribing Information injection form (3E) (available at www.Keppra.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 pharmaceutical and biotechnology products in the fields of central nervous system disorders, allergy/respiratory diseases, immune and inflammatory disorders and oncology. UCB focuses on securing a leading position in severe disease categories. Employing more than 10,000 people in over 40 countries, UCB achieved revenue of 3.5 billion euro in 2006 on a pro forma basis. UCB S.A. is listed on the Euronext Brussels Exchange and through its affiliate. SCHWARZ PHARMA AG (Monheim, Germany) is a member of the UCB Group.

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 its employees.