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Press Release

Keppra® Approved for US Epilepsy Patients with One of the Most Debilitating Seizure Types

FDA approves Keppra® for primary generalized tonic-clonic seizures in adults and children aged 6 and older

Brussels, Belgium – March 20, 2007 – 8:30 pm CET – The US Food and Drug Administration (FDA) has approved UCB's leading anti-epileptic drug Keppra® (levetiracetam), as adjunctive therapy in the treatment of primary generalized tonic-clonic (PGTC) seizures in adults and children 6 years of age and older with idiopathic generalised epilepsy (IGE). In epidemiological studies generalized seizures account for about 40% of incidence cases, with generalized tonic-clonic seizures estimated at 23%.[1] The new indication, which is the fourth for Keppra® tablets and oral solution in the US, and the second for a generalized seizure type[3] confirms the broad spectrum efficacy of Keppra®. This US approval closely follows the European Commission approval for Keppra® in this debilitating generalized seizure type earlier this year.

'Almost one in four people with epilepsy have tonic-clonic seizures which are one of the most recognizable seizure types beginning with a sudden loss of consciousness and stiffening of the muscles, followed by rapid rhythmic jerking of the arms and legs.' said Dr. Robert C. Knowlton of UAB Epilepsy Centre, Birmingham, Alabama, US. He continued, '*Seizure freedom, with minimal side*

effects is the ultimate goal for physicians and patients. In the trial supporting this new indication higher seizure freedom rates were observed for patients taking Keppra® compared to those taking placebo. *These results support the growing evidence for Keppra® as an effective adjunctive therapy across partial and generalised seizure types*.'

In a multicenter, randomized, double-blind, placebo-controlled clinical trial of Keppra® as add-on treatment in 164 patients (four-65 years of age) with refractory IGE, nearly a quarter (24.1%) achieved complete seizure freedom from all seizure types over the 20 week evaluation period .[2] This compared with only 8.3% of those who received a placebo in addition to their usual treatment (*p=0.009*)[1]. Nearly three quarters (72.2%) of those who took Keppra® achieved a 50% reduction in weekly PGTC seizures, compared to less than half (45.2%) of those in the placebo group (*p<0.001*).[2] In this well-controlled clinical study, the most frequently reported adverse event was nasopharyngitis (14% in Keppra® patients compared with 5% in patients taking placebo).[3]

Keppra® is already approved in the US as[3,4]:

- Adjunctive therapy in the treatment of partial onset seizures in adults and children (>4 years of age) with epilepsy
- Adjunctive therapy in the treatment of myoclonic seizures in adults and adolescents (>12 years of age) with Juvenile Myoclonic Epilepsy (JME)

'*People with epilepsy want to be free to get on with their everyday lives. This latest indication for Keppra® supports its broad spectrum of efficacy across partial and generalised seizures types. We are pleased that there is now an opportunity for patients with one of the most debilitating seizure types – primary generalized tonic-clonic seizures - to benefit from Keppra®',* said Troy Cox, President CNS Operations, UCB.

About Keppra® in the US[3]

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, as adjunctive therapy in the treatment of myoclonic seizures in adults and adolescents 12 years of age and older with juvenile myoclonic epilepsy, and as adjunctive therapy in the treatment of primary generalized tonic-clonic seizures in adults and children 6 years of age and older with idiopathic generalized epilepsy (IGE). Keppra® is associated with the occurrence of central nervous system adverse events including somnolence and fatigue and behavioral abnormalities, as well as hematological abnormalities. In adults experiencing partial onset seizures, Keppra® is also associated with coordination difficulties. In pediatric patients 4-16 years of age experiencing partial onset seizures, the most common adverse events associated with Keppra® in combination with other antiepileptic drugs (AEDs) were somnolence, accidental injury, hostility, nervousness and asthenia. 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 adults and adolescents 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 adults and children 6 years of age and older with idiopathic generalized epilepsy experiencing primary generalized tonic-clonic seizures, the most common adverse event associated with Keppra® in combination with other AEDs was nasopharyngitis. Keppra® is also available as an intravenous formulation for the adjunctive treatment of partial-onset seizures in adults with epilepsy. Keppra® injection is an alternative for patients when oral administration is temporarily not feasible. The adverse events that may result from Keppra® injection use for partial onset seizures include all those associated with Keppra® tablets and oral solution. For the U.S., prescribing information is available at www.keppra.com.

About Keppra® in Europe[5]

Keppra® is indicated as monotherapy in the treatment of partial onset seizures with or without secondary generalisation in patients from 16 years of age with newly diagnosed epilepsy; as adjunctive therapy in the treatment of partial onset seizures with or without secondary generalisation in adults and children from 4 years of age with epilepsy; as adjunctive therapy in the treatment of myoclonic seizures in adults and adolescents from 12 years of age with JME and as adjunctive therapy in the treatment of PGTC seizures in adults and adolescents from 12 years of age with IGE. In monotherapy the most commonly reported side effects were fatigue and somnolence. As adjunctive therapy in adults with partial onset seizures the most commonly reported side effects were somnolence, asthenia and dizziness. As adjunctive therapy in paediatric patients (4-16 years of age) with partial onset seizures the most commonly reported side effects were somnolence, hostility, nervousness, emotional lability, agitation, anorexia,

asthenia and headache. In adults and adolescents with myoclonic seizures the most common reported side effects associated with Keppra® in combination with other AEDs were headache and somnolence. In adults and adolescents with primary generalized tonic-clonic seizures the most common reported side effects associated with Keppra® in combination with other AEDs was fatigue. Keppra® is also indicated for intravenous administration and is available as 100 mg/mL concentrate for solution for infusion[3]. The most common adverse events from Keppra® intravenous use were dizziness, somnolence, headache and postural dizziness. Please consult local prescribing information.

About UCB

Headquartered in Brussels (Belgium), UCB (www.ucb-group.com <http://www.ucb-group.com>) is a leading global biopharmaceutical company 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 8400 people in over 40 countries, UCB achieved revenue of 2.5 billion euro in 2006. UCB is listed on the Euronext Brussels Exchange and owns 87.6% of Schwarz Pharma.

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2. Rosenfeld WE, Berkovic S, Knowlton R on behalf of Lev N01057 PGTC Study Group – Efficacy and Safety of Levetiracetam 3000 mg/day (Padiatric Dose 60 mg/kg/day) as Adjunctive Therapy in Adult and Pediatric Idiopathic Generalized Epilepsy Patients Experiencing Primary Generalized Tonic-Clonic Seizures (Poster Presentation) 1st North American Regional Epilepsy Congress 2006, San Diego, Dec 1-5, 2006
3. U.S. Prescribing Information oral dose forms (23E) (available at www.Keppra.com)
4. U.S. Prescribing Information injection form (2E) (available at www.Keppra.com)
5. Summary of Product Characteristics