# UCB Announces FDA Filing for *lacosamide* in the Treatment of Partial Onset Seizures in Adults with Epilepsy

## U.S. Food and Drug Administration (FDA) has accepted for filing the New Drug Application (NDA) for the use of Vimpat™ (*lacosamide*) as adjunctive therapy in the treatment of partial onset seizures in adults with epilepsy.

**Brussels (BELGIUM), November 29, 2007 at 7:00 am CET –** UCB announced today that the U.S. Food and Drug Administration has accepted for filing the New Drug Application (NDA) for the use of *lacosamide* as adjunctive therapy in the treatment of partial onset seizures in adults with epilepsy. The application includes three *lacosamide* formulations – tablets, syrup and an intravenous injection. The proposed trade name for *lacosamide* is Vimpat™.

"This filing is another step in support of UCB's epilepsy franchise and its long-term commitment to advancing treatment options for patients with epilepsy," said Iris Loew-Friedrich, MD, PhD, Global Head of Development, UCB.

The NDA for *lacosamide* in epilepsy is supported by data from three clinical trials with a total of approximately 1,300 adults with uncontrolled partial onset seizures, despite taking one to three antiepileptic drugs (AEDs).[1,2,3] In these studies, significantly greater 50% responder rates and reductions in median seizure frequency were seen versus placebo.[1,2,3] The most common adverse events of *lacosamide* (≥10%) reported in these trials included dizziness, headache, nausea and diplopia.[1,2,3]

A similar filing made to the European Medicines Agency (EMEA) earlier this year for the use of *lacosamide* as adjunctive therapy in the treatment of partial onset seizures in adults with epilepsy, was accepted and is currently under review.

**About Epilepsy** [4,5,6]**:** 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 *Lacosamide*** [7,8,9]**:** *Lacosamide* has a novel and dual mode of action. It selectively enhances slow inactivation of sodium channels and interacts with the neuroplasticity-relevant target - collapsin-response mediator protein-2 (CRMP-2).

***References***


1. Chung, S., Sperling, M., Biton, V., Krauss, G., Doty, P., Sullivan T. and the SP745 Study Group. *Lacosamide*: Efficacy and Safety as Oral Adjunctive Treatment in Adults with Partial Onset Seizures. Poster Presentation, 11th EFNS, Brussels 25-28 August 2007
2. Halász P, Kälviäinen R, Mazurkiewicz-Beldzinska M, Rosenow F, Doty P, Sullivan P and the SP755 Study Group *Lacosamide*: Efficacy and Safety as Oral Adjunctive Therapy in Adults with Partial Seizures Poster Presentation, 11th EFNS, Brussels 25-28 August 2007
3. Ben-Menachem E, Biton V, Jatuzis D, Abou-Khalil B, Rudd GD and the SP667 Study Group. Efficacy and Safety of Adjunctive Oral *Lacosamide* for the Treatment of Partial Onset Seizures in Patients with Epilepsy as Oral Adjunctive Therapy in Adults with Partial Seizures. Poster Presentation, 11th EFNS, Brussels 25-28 August 2007
4. 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
5. European White Paper on Epilepsy, EUCARE 2001
6. http://www.who.int/whr/1997/media_centre/50facts/en/index.html (Accessed October 9th 2007)
7. Heers, C, Beyreuther, B., Freitag, J., Lees, G. Errington A., Stöhr, T: *Lacosamide* selectively enhances sodium channel slow inactivation. Poster Presentation, 11th EFNS, Brussels, 25-28 August 2007
8. Freitag, J., Beyreuther, B., Heers, C, Stöhr, T. (2007) *Lacosamide* interacts with collapsin response mediator protein 2 (CRMP 2). Poster Presentation, 11th EFNS, Brussels, 25-28 August 2007
9. Beyreuther BK, Freitag J, Heers C et al. *Lacosamide*: a review of preclinical properties.CNS Drug Reviews 2007;13 (1), 21–42


***Further information***


*Antje Witte, Vice-President Corporate Communications & Investor Relations, UCB Group*
*T +32.2.559.9414, Antje.witte@ucb-group.com*

*Mareike Mohr, Associate Director Investor Relations, UCB Group*
*T +32.2.559.9264, Mareike.mohr@ucb-group.com*


***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, owns approx. 89% of the shares of SCHWARZ PHARMA AG. SCHWARZ PHARMA (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.*