



## UCB Announces FDA Filing for *lacosamide* in the Treatment of Diabetic Neuropathic Pain

**U.S. Food and Drug Administration (FDA) has accepted for filing the New Drug Application (NDA) for the use of Vimpat™ (*lacosamide*) in the treatment of adults with diabetic neuropathic pain.**

**Brussels (BELGIUM), November 29, 2007 at 7:00 am CET** – UCB announced today that the U.S. Food and Drug Administration (FDA) has accepted for filing the New Drug Application (NDA) for the use of *lacosamide* in the treatment of diabetic neuropathic pain. The application relates to the tablet formulation of *lacosamide*, whose proposed trade name is Vimpat™.

"The fact that a high proportion of patients with diabetic neuropathic pain do not achieve satisfactory pain relief with current management options is a powerful stimulus to research and develop new therapies." said Iris Loew-Friedrich, MD, PhD, Global Head of Development, UCB. "The FDA acceptance for review means that a full assessment will be carried out on *lacosamide*'s potential to provide sustained pain relief in patients with moderate to severe diabetic neuropathic pain."

In placebo-controlled clinical trials of over 800 people with diabetic neuropathic pain, significant and sustained reductions in pain scores were seen versus placebo.<sup>1,2,3</sup> The pain relief achieved with *lacosamide* was associated with reduced interference with sleep and general activities.<sup>1</sup> The most common adverse events of *lacosamide* (≥10%) reported in these trials included dizziness, nausea, tremor and headache.<sup>1,2,3</sup>

A similar filing made to the European Medicines Agency (EMA) earlier this year for the use of *lacosamide* in the treatment of diabetic neuropathic pain, was also accepted and is currently under review.

**About Diabetic Neuropathic Pain**<sup>4,5</sup>: Diabetic Neuropathic Pain is a painful and potentially debilitating condition, resulting from damage or dysfunction to the peripheral nervous system as a result of diabetes or impaired glucose tolerance. The condition is often characterized by a stabbing or burning sensation in the legs, feet, and/or hands. With the overall prevalence of diabetes in the U.S. estimated at 20.8 million people, it is thought that as many as 7.7 million have some degree of diabetic neuropathic pain.

**About *lacosamide***<sup>4,6,7</sup>: *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



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5. Nicholson B. Differential diagnosis: nociceptive and neuropathic pain. Am J Manag Care 2006;12, S256-S262
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#### **Further information**

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#### **About UCB**

UCB, Brussels, Belgium ([www.ucb-group.com](http://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.*