

## New Phase III Trial Shows Positive Outcome of *lacosamide* in Patients with Diabetic Neuropathic Pain

# Sustained improvements in daily pain scores demonstrated in the latest study with Vimpat<sup>™</sup> (*lacosamide*)

**Brussels (Belgium)**, **11 December 2007 at 7:00 AM (CET)**: UCB announced today positive results from a Phase III trial evaluating *lacosamide* (400 mg per day) in the treatment of diabetic neuropathic pain. With a standard titration regimen, the trial met its primary objective with sustained and statistically significant reduction in average daily pain scores.

"These new results add to the data from earlier clinical studies showing the benefit of *lacosamide* in this painful and common complication of diabetes," said Iris Loew-Friedrich, MD, PhD, Global Head of Development, UCB Group.

The randomised, double-blind, placebo controlled trial in 551 patients with diabetic neuropathic pain was designed to evaluate the efficacy and safety of *lacosamide* (400mg per day) in two different titration schemes: a standard titration regimen in which patients reached their target dose at day 22, and a fast titration scheme in which the target dose was reached at day 8.

The primary efficacy results showed that the change in the average daily pain score as measured from baseline to the last four weeks of the 12-week maintenance period, was significantly greater with *lacosamide* 400mg per day given in standard titration than placebo (p=0.0410). The change in pain score with the *lacosamide* fast titration regimen was numerically better than placebo but did not reach statistical significance (p=0.2902). The median time to achieve sustainable pain relief was 10 and 11 days for the *lacosamide* standard and fast titration regimens, respectively compared with 31 days for the placebo group. *Lacosamide* was generally well tolerated. The incidences of adverse events were higher in the *lacosamide* fast titration group than in the standard titration group. The most common adverse events ( $\geq$ 5%) in this trial were dizziness, nausea, headache, nasopharyngitis and vertigo.

The results from this trial will support the dossiers filed for *lacosamide* in diabetic neuropathic pain which were submitted to the European and U.S. regulatory authorities earlier this year. Data from this trial will be submitted for presentation at upcoming international scientific meetings.



**About Diabetic Neuropathic Pain**<sup>1,2</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>3,4</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

- 1. Beyreuther BK, Freitag J, Heers C et al. Lacosamide: a review of preclinical properties.CNS Drug Reviews 2007;13 (1), 21–42
- 2. Nicholson B. Differential diagnosis: nociceptive and neuropathic pain. Am J Manag Care 2006;12, S256-S262
- 3. Heers, C, Beyreuther, B., Freitag, J., Lees, G. Errington A., Stöhr, T.: Lacosamide selectively enhances sodium channel slow inactivation. Poster Presentation, 11th EFNS, Brussels, 2007
- 4. Freitag, J., Beyreuther, B., Heers, C, Stöhr, T. Lacosamide interacts with collapsin response mediator protein 2 (CRMP 2). Poster Presentation, 11th EFNS, 2007

### Further information

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### About UCB

UCB, Brussels, Belgium (<u>www.ucb-group.com</u>) 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 around 12,000 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.

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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.