



UCB withdraws EU marketing authorisation application for lacosamide in diabetic neuropathic pain

Brussels, BELGIUM, September 25, 2008 at 06:00 pm CET - press release, regulated information: UCB announced today that it is withdrawing the European Marketing Authorisation Application with the European Medicines Agency (EMA) for Vimpat® (lacosamide) in the treatment of diabetic neuropathic pain.

UCB has taken this decision based on the EMA's Committee for Medicinal Products for Human Use (CHMP) view that the magnitude of the clinical effect of lacosamide in diabetic neuropathic pain has not been convincingly established. Following thorough consultation with the agency, UCB would need to initiate an additional clinical trial to further substantiate the magnitude of effect of lacosamide in diabetic neuropathic pain.

Vimpat® was approved by the European Commission for the adjunctive treatment of partial-onset seizures with or without secondary generalisation in patients with epilepsy, aged 16 years and over, at the end of August. The product is being launched in the EU from mid-September 2008.

Vimpat® is currently under active review by the U.S. Food and Drug Administration (FDA) for the adjunctive treatment of partial-onset seizures in patients with epilepsy, aged 16 years and over.

At the end of July, UCB announced that it had received an action letter (not-approvable letter) from the U.S. FDA for lacosamide for the treatment of diabetic neuropathic pain in adults.

The financial guidance for 2008 and 2009 given by UCB remains unchanged.

About Diabetic Neuropathic Pain

Diabetic neuropathic pain is a painful and potentially debilitating complication of diabetes often characterized by a stabbing or burning sensation in the legs, feet and/or hands. It is caused by damage or dysfunction to the peripheral nervous system as a result of diabetes or impaired glucose tolerance. Diabetic neuropathic pain often substantially interferes with sleep, recreational activities, mobility, and normal work and social activities, and many patients with the condition experience a significantly reduced quality of life.

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 medicines with a focus on the fields of central nervous system and immunology disorders. Employing around 12 000 people in over 40 countries, UCB achieved revenue of 3.6 billion Euro in 2007. UCB is listed on Euronext Brussels (symbol: UCB).

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.