UCB's Vimpat™ recommended for approval in Europe for epilepsy

Brussels, BELGIUM, June 26, 2008 – Press release: regulated information
UCB announced today that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMEA) has issued a positive opinion recommending that the European Commission grants a marketing authorisation for lacosamide, proposed trade name Vimpat™, for the adjunctive treatment of partial onset seizures with or without secondary generalisation in patients with epilepsy, aged 16 years and older.

The recommendation has been granted for the oral tablet, oral syrup and intravenous formulations.

"The European positive opinion for approval of Vimpat™ marks a major achievement for patients with epilepsy whose seizures are not well controlled by current antiepileptic drugs, and for UCB, strengthening our leadership in treatments for this severe disease," said Roch Doliveux, CEO, UCB. "Today also represents another significant step forward for UCB in our strategic execution with another innovative medicine to be approved."

The CHMP decision is supported by data from three multicentre, double blind, placebo controlled clinical trials that evaluated the efficacy, safety and tolerability of lacosamide (200, 400 and 600 mg/day given in two divided doses) in a total of over 1,300 adults with uncontrolled partial onset seizures. Patients in these trials were taking at least one to three antiepileptic drugs (AEDs) and many of the patients had previously tried at least seven AEDs.

Across these studies significantly greater than 50% responder rates and reductions in median seizure frequency were seen versus placebo. Lacosamide was also generally well tolerated with the most common adverse events of lacosamide (≥10% and greater than placebo) reported in these trials including dizziness, nausea, diplopia and headache.

"With as many as 30 per cent of epilepsy patients continuing to have seizures despite treatment with antiepileptic drugs, there is a need for new, efficacious and well tolerated treatment options," said Professor Elinor Ben-Menachem, Department of Clinical Neuroscience, Goteborg University, Sweden. "These clinical studies suggest that adjunctive lacosamide may be a useful pharmacological treatment option for patients with partial onset seizures."

Regulatory filings for Vimpat™ oral tablet, oral solution and intravenous formulation are currently also under review by the US Food and Drug Administration (FDA) for use as adjunctive therapy in the treatment of partial onset seizures in adults with epilepsy. Vimpat™, oral tablet, is currently under review by the EMEA and the US FDA for the treatment of diabetic neuropathic pain.

About Epilepsy: Epilepsy is a chronic neurological disorder affecting 50 million people worldwide. It is caused by abnormal, excessive electrical discharges of the nerve cells or neurons in the brain. Epilepsy is characterised 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: Lacosamide has a dual mode of action and is the first agent of its kind to be clinically studied for the treatment of epilepsy. It selectively enhances slow inactivation of sodium channels and interacts with the neuroplasticity-relevant target – collapsin-response mediator protein-2 (CRMP-2).

Further information

Antje Witte, Vice-President Corporate Communications & Investor Relations, UCB Group
T +32.2.559.9414, Antje.witte@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 around 12,000 people in over 40 countries, UCB achieved revenue of EUR 3.6 billion in 2007. UCB S.A. is listed on the Euronext Brussels Exchange.

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.