

UCB Announces Initiation of Phase III Clinical Program for Rikelta[™] (*brivaracetam*) as Adjunctive Treatment in Partial-Onset Epilepsy

Brussels (BELGIUM), October 26, 2007 at 7:00 am CET – Phase III clinical trials of UCB's antiepileptic drug (AED) in development, *brivaracetam*, are underway, as adjunctive therapy in patients with refractory partial-onset epilepsy. Rikelta[™] is the proposed tradename for *brivaracetam*.

"The start of the Phase III program for brivaracetam is a key milestone in the advancement of UCB's epilepsy franchise and re-enforces our commitment to the development of new treatment options for people with epilepsy," said Iris Loew-Friedrich, MD, PhD, Global Head of Development, UCB. "Today up to 30% of patients can be resistant to current antiepileptic medications and UCB's research and development programmes aim to support this significant unmet medical need."

Nearly 1300 epilepsy patients, aged between 16 and 70 years, will take part in three multicentre, multinational phase III trials. Two randomized, double-blind, placebo-controlled studies are designed to evaluate the efficacy and safety of *brivaracetam* (5, 20 and 50 mg/day or 20, 50 and 100 mg/day) over 12 weeks in patients with partial onset epilepsy, not fully controlled despite treatment with one or two other antiepileptic drugs. The third study is a randomized, double-blind, placebo-controlled trial with flexible dosing designed to evaluate the safety and tolerability of *brivaracetam* in patients with uncontrolled partial onset or primary generalised seizures. First results are expected in Q3 2009.

The move to Phase III development follows promising efficacy and tolerability data for *brivaracetam* in two phase IIb dose ranging studies. These trials were conducted in patients with uncontrolled partial onset seizures despite taking one or two antiepileptic drugs, and included patients taking Keppra[®]. Data from these double blind, randomized, placebo-controlled studies were reported at the 27th International Epilepsy Congress (IEC) held in Singapore in July 2007.^{1,2}

About brivaracetam ^{3,4}

Brivaracetam has distinct pharmacological differences as well as having some structural similarity to Keppra[®]. In preclinical studies *brivaracetam* was shown to have a 10-fold higher affinity for synaptic vesicle protein 2A (SV2A) than Keppra[®]. *Brivaracetam* also has inhibitory activity at neuronal voltage-dependent sodium channels whose abnormal function is understood to contribute to



electrical discharges associated with seizures. These differences may be important for *brivaracetam*'s antiepileptic activity, clinical efficacy and tolerability.

About Epilepsy 5,6

Epilepsy is the most common chronic serious disorder of the central nervous system and can affect people of all ages. Over 40 million people worldwide have epilepsy. It is caused by abnormal, excessive electric 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.

References

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- van Paesschen W, von Rosenstiel P on behalf of the *Brivaracetam* N01114 Study Group. Presented at the 27th International Epilepsy Congress, Singapore, 8-12 July 2007
- 3. Kenda BM, Matagne AC, Talaga PE et al. Discovery of 4-substituted pyrrolidone butanamides as new agents with significant antiepileptic activity. J Med Chem 2004; 47: 530-549.
- Zona C, Pieri M, Klitgaard H et al. UCB 34714 (*brivaracetam*) a new pyrrolidone derivative inhibits Na²⁺ currents in rat cortical neurons in culture. Presented at the 58th Annual Meeting of the American Epilepsy Society, New Orleans, 2004.
- 5. European White Paper on Epilepsy
- 6. <u>http://www.who.int/whr/1997/media_centre/50facts/en/index.html</u> (Accessed October 9th 2007)

Further information

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

Mareike Mohr, Associate Director Investor Relations, UCB Group T +32.2.559.9264, <u>Mareike.mohr@ucb-group.com</u>

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 AG (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.