UCB delivers on its clinical development milestones

- **Brivaracetam: new Phase III study started**
- **Vimpat®: European monotherapy study initiated**
- **Vimpat®: first results from the Phase II paediatric studies**
- **Epratuzumab started Phase III program**
- **CDP6038 (anti-IL6): Phase IIb program initiated ahead of plan**

Brussels (Belgium), 10 January 2011, 07:00 AM (CET) – regulated information – UCB today announced that four major clinical development milestones have been achieved as planned plus one ahead of schedule during the fourth quarter of 2010.

A new Phase III study evaluating ***brivaracetam*** as adjunctive therapy in the treatment of partial onset seizures in adults with epilepsy has commenced with the first patient first visit recorded in December 2010. It is a randomized, double-blind, placebo-controlled, multicentre, parallel-group study with more than 700 patients to evaluate the efficacy and safety of *brivaracetam* 100 mg/day and 200 mg/day on seizure frequency. The headline results are expected in the first half 2013.

UCB also initiated a Phase III clinical study across Europe to evaluate the efficacy and safety of **Vimpat®** (*lacosamide*) (200 to 600 mg/day) as monotherapy in adult patients newly or recently diagnosed with epilepsy and experiencing partial-onset seizures or generalized tonic-clonic seizures. It is a multicenter, double-blind, double-dummy, randomized study comparing *lacosamide* (200mg to 600mg/day) with *carbamazepine* controlled release (400mg to 1200mg/day). The non-inferiority design is intended to show at least a similar benefit-risk balance between *lacosamide* and *carbamazepine* controlled release. The headline results for this trial are expected by the end of 2014.

The first results from the Phase II programme investigating **Vimpat®** as adjunctive therapy in children aged 2-17 years with uncontrolled partial-onset seizures are now available. The profile for *lacosamide* in children aged 5-11 years is similar to that observed in healthy adults. No evidence for dose dependent increase in treatment related adverse events and no clinically relevant changes observed in laboratory values and vital signs. Data from this study were used to determine the dose range for the subsequent paediatric studies being performed.

In December 2010, UCB announced the enrollment of the first patient into its Phase III programme (EMBODY™ 1 and EMBODY™ 2) for ***epratuzumab*** in patients with moderate to severe systemic lupus erythematosus (SLE). Recruitment is ongoing with approximately 780 subjects randomized in each study to be recruited. First results are expected in the first half 2014.

A Phase IIb programme for **CDP6038** (anti-IL 6) being developed for the treatment of moderate to severe rheumatoid arthritis started ahead of plan with first patients recruited and multiple study sites now active. It is a randomized, double-blind placebo-controlled, dose ranging study in more than 200 patients with an active comparator to evaluate the efficacy and safety of CDP6038 administered subcutaneously for 12 weeks to patients with active rheumatoid arthritis having previously failed TNF blocker therapy. The headline results are expected in the third quarter 2012.

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Notes to the editor

About UCB
UCB, Brussels, Belgium (www.ucb.com) is a global biopharmaceutical company focused on the discovery and development of innovative medicines and solutions to transform the lives of people living with severe diseases of the immune system or of the central nervous system. With more than 8 000 people in about 40 countries, the company generated revenue of EUR 3.1 billion in 2009. 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 employees.