



## UCB announces top-line outcomes for proof-of-concept studies

**Lacosamide in migraine prophylaxis and rotigotine in fibromyalgia syndrome did not achieve statistical significance for their primary endpoints**

**Brussels, Belgium, 20 February 2009 at 6:00 PM (CET) – press release, regulated information** - UCB announced today top-line results from two proof-of-concept Phase IIa clinical trials to assess the efficacy and safety of lacosamide in migraine prophylaxis, and the efficacy and safety of rotigotine in fibromyalgia syndrome. These trials were designed to determine whether there is justification for further clinical development of lacosamide and rotigotine in these indications. The respective studies did not achieve statistical significance for their primary endpoints. UCB will evaluate development plans once full analyses are available.

### **Phase IIa study: lacosamide in migraine prophylaxis**

The multicentre, randomized, double-blind, placebo-controlled trial was designed to evaluate the efficacy of lacosamide (100 mg/day and 300 mg/day) compared to placebo in reducing the frequency of migraine. The primary efficacy variable was the mean reduction of migraine rates during the 14-week maintenance period compared to the average frequency during the 4-week baseline period. Patients in this trial (218) had a history of episodic migraine with or without aura for at least 1 year and a well-documented three month retrospective history of migraines prior to enrolment. The trial did not meet its primary endpoint. However, a reduction in headache frequency was consistently observed in all treatment groups.

### **Phase IIa study: rotigotine in fibromyalgia syndrome**

The multicentre, randomized, double-blind, placebo-controlled trial was designed to investigate the efficacy and safety of rotigotine (4 mg/24 h and 8 mg/24 h) compared to placebo in adult patients (240) with signs and symptoms of fibromyalgia syndrome. The primary efficacy variable was the reduction in pain for patients taking rotigotine as measured by the average Likert pain score at baseline to the last two weeks of the 13 week treatment period. The study results did not achieve statistical significance for its primary endpoint. Only primary efficacy and safety data have been reviewed at this time.

### **About UCB**

*UCB, Brussels, Belgium ([www.ucb.com](http://www.ucb.com)) is a biopharmaceutical company dedicated to the research, development and commercialization of innovative medicines with a focus on the fields of central nervous system and immunology disorders. Employing more than 10 000 people in over 40 countries, UCB aims to achieve revenues of at least EUR3.3 billion in 2008. UCB is listed on Euronext Brussels (symbol: UCB).*

### **For further information**

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**About Migraine**

*Migraine is a common, disabling primary headache disorder. It typically affects one side of the head and may be pulsating, of moderate to severe intensity, and aggravated by routine activity. Migraine headache can last up to two to three days and is commonly accompanied by nausea and vomiting, and/or intolerance to normal levels of light and sound. Migraine is two to three times more common in women than men.*

**About Fibromyalgia**

*Fibromyalgia is an idiopathic, chronic, pain syndrome defined by widespread musculoskeletal pain and generalized tender points. Other common symptoms include sleep disturbances, fatigue, headache, morning stiffness and anxiety. Fibromyalgia is usually considered a disorder of women aged 20 to 50 years; however, it has also been observed in men, children, adolescents and older persons. Fibromyalgia is more common in relatives of people with fibromyalgia, suggesting the contribution of genetic factors.*

**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.*