Xyrem® not recommended for fibromyalgia syndrome in the EU

BRUSSELS, Belgium, 17 March 2011 – 18:00 (CET) – press release, regulated information - UCB announced today that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) informed UCB that Xyrem® (sodium oxybate) will not be recommended as a treatment for fibromyalgia syndrome in adults.

"Upon discussions and following oral explanation with the CHMP, we have to accept that Xyrem® in fibromyalgia syndrome will not be recommended for approval in the EU near-term. We are very disappointed with the CHMP decision given the significant unmet medical need in fibromyalgia syndrome in Europe today and the consistently positive phase 3 clinical trials with Xyrem® in the indication," said Prof. Iris Loew-Friedrich, Chief Medical Officer, UCB.

No medication has been approved in Europe to date for the treatment of fibromyalgia which is a chronic disease characterized by widespread pain.

In the European Union sodium oxybate is approved for the treatment of narcolepsy with cataplexy in adult patients and is marketed by UCB under a license from Jazz Pharmaceuticals.

Xyrem® (sodium oxybate) in the European Union/EEA Important Safety Information
Xyrem® is an oral solution that contains the active substance sodium oxybate (500 mg/ml). Xyrem® is indicated for the treatment of narcolepsy with cataplexy in adults.

Contraindications: Hypersensitivity to the active substance or to any of the excipients. Patients with succinic semialdehyde dehydrogenase deficiency and in patients being treated with opioids or barbiturates. Special warnings and precautions for use: Sodium oxybate has the potential to induce respiratory depression. Because sodium oxybate can be abused, physicians should evaluate patients for a history of drug abuse and follow such patients closely. Patients should be warned against the use of alcohol in conjunction with sodium oxybate. Sodium oxybate is considered to be unsafe in patients with porphyria. The concomitant use of benzodiazepines and sodium oxybate should be avoided. Patients may become confused while being treated with sodium oxybate and if this occurs they should be evaluated carefully and appropriate intervention considered on an individual basis. Patients with a previous history of a depressive illness and/or suicide attempt should be monitored especially carefully for the emergence of depressive symptoms while taking sodium oxybate. Undesirable effects: The most commonly reported adverse reactions are dizziness, headache and nausea, all occurring in 10%-20% of patients.

For the full list of all side effects associated with Xyrem® please consult

http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Product_Information/human/000593/WC500057103.pdf [Accessed 21st Feb 2011]

In the U.S. Xyrem® is marketed by Jazz Pharmaceuticals for the treatment of excessive daytime sleepiness and cataplexy (the sudden loss of muscle tone) in adult patients with narcolepsy.

About Fibromyalgia
Fibromyalgia, a chronic condition characterized by widespread pain, affects 0.5% - 5% of adults worldwide. Fibromyalgia is believed to be a central nervous system condition, resulting from neurological changes in how the brain perceives and responds to pain. In addition to pain, the main symptoms are fatigue, disturbed sleep and morning stiffness. The exact causes of fibromyalgia are

unknown. It may be triggered by physical trauma, emotional stress, chronic pain or infection. Genetics, neurochemicals that affect pain modulation, neurohormones and sleep physiology abnormalities are thought to play a role. Research also has suggested a relationship between sleep and pain. Fibromyalgia patients experience a high prevalence of sleep problems, including a reduction in restorative or deep sleep.

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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 8 500 people in about 40 countries, the company generated revenue of EUR 3.2 billion in 2010. UCB is listed on Euronext Brussels (symbol: UCB).

Forward-looking statements
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.