

Press Release

European Medicines Agency Adopts Positive Opinion Recommending Approval of Xyrem[®] for the Treatment of Narcolepsy with Cataplexy in Adult Patients

Brussels, Belgium, 25 January 2007 – 5:30 PM CET - UCB today announced 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 marketing authorisation for Xyrem[®] (sodium oxybate) in the treatment of narcolepsy with cataplexy in adult patients. The European Commission is expected to issue a decision within approximately six weeks.

Narcolepsy is a debilitating, life-long disorder. Typically beginning with excessive daytime sleepiness during the second and third decades of life, narcolepsy usually progresses to include disturbed night-time sleep, cataplexy, sleep paralysis and hypnagogic hallucinations.

Troy Cox, President CNS Operations, UCB said, 'This positive opinion is encouraging news and we now look forward to the opportunity of making Xyrem[®] available to more patients in Europe with this sleep disorder. With this expanded indication, Xyrem[®] would be the first and only medicine approved by the European Medicines Agency for the treatment of narcolepsy with cataplexy in adult patients.'

The effectiveness of Xyrem[®] for the treatment of narcolepsy symptoms has been established in three multi-centre, double-blind, placebo-controlled studies¹⁻³. The long term safety and efficacy of Xyrem[®] for the treatment of narcolepsy has also been evaluated in a 12-month, open-label, multicentre extension trial⁴.

About Xyrem[®] in Europe⁵

Xyrem[®] was designated as an orphan medicinal product on 3 February 2003. Orphan medicinal products are used to diagnose, prevent or treat life-threatening or very serious conditions that are rare, with a prevalence of less than five per 10,000 of the EU population.

Xyrem[®] is indicated in Europe for the treatment of cataplexy in adult patients with narcolepsy. Sodium oxybate, the active ingredient in Xyrem[®], is a sodium salt of gamma- hydroxybutyrate.

The most commonly reported adverse drug reactions are dizziness, nausea, and headache, all occurring in 10 % to 20 % of patients. Sodium oxybate is contraindicated in patients with succinic semialdehyde dehydrogenase deficiency. Sodium oxybate is contraindicated in patients being treated with opiods or barbiturates.

Please refer to the Xyrem[®] SmPC for full prescribing information.

About Narcolepsy

Narcolepsy is a chronic, debilitating neurological disease, the primary symptoms of which are excessive daytime sleepiness (EDS), fragmented nighttime sleep, and cataplexy. The hallmark symptom of narcolepsy is excessive and overwhelming daytime sleepiness, even after nighttime sleep. EDS is present in all narcolepsy patients and causes patients to become drowsy or fall asleep, often at inappropriate times and places. Cataplexy, the sudden loss of muscle tone, is the most predictive symptom of narcolepsy. Cataplexy can range from slight weakness or a drooping of the face to the complete loss of muscle tone and is triggered by strong emotional reactions such as laughter, anger or surprise.

About UCB

UCB (<u>www.ucb-group.com</u>) is a leading global biopharmaceutical company 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 over 8,300 people in over 40 countries, UCB achieved revenue of 2.3 billion euro in 2005. UCB is listed on the Euronext Brussels Exchange. Worldwide headquarters are located in Brussels, Belgium.

Further information:

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- 4. U.S. Xyrem[®] Multicenter Study Group A 12-month, Open-Label, Multicenter Extension Trial of Orally Administered Sodium Oxybate for the Treatment of Narcolepsy *Sleep* 2003: 26 (1), 31-35
- 5. Xyrem[®] SmPC Europe