UCB S.A. 60 Allée de la Recherche, B-1070 Brussels (Belgium)

Press Release

Xyrem® is Launched in Germany for the Treatment of Cataplexy in Adults with Narcolepsy

Brussels, Belgium – December 8, 2005: UCB announced today that Xyrem® (sodium oxybate) oral solution is now available in Germany for the treatment of cataplexy in adult patients with narcolepsy. Launch in this first major European market follows the recent European Commission (EC) marketing approval of Xyrem® in this orphan indication, with pan-European commercialisation expected over 2006.

"Xyrem® provides physicians and patients in Europe with the first and only EMEA approved medication for the treatment of cataplexy in patients with narcolepsy. We are delighted to serve European physicians and sleep centres with a product that can help fulfil the unmet medical need in patients with this serious sleep disorder." said Emmanuel Caeymaex, Vice-President, Marketing CNS, UCB.

Narcolepsy is a debilitating, life-long neurological disorder that is characterised by excessive daytime sleepiness and sleep attacks[1]. Cataplexy is a typical symptom of narcolepsy and is present in 65-70% of patients with narcolepsy. It involves a sudden reversible loss of muscle tone, usually triggered by emotional stimuli such as laughter, excitement, surprise and anger, with contributing factors including physical fatigue, stress or sleepiness[2].

Commenting on the marketing approval Adrian Williams MD of Sleep Centre, St. Thomas Hospital, London, UK said “Patients and physicians in the EU should be encouraged by the body of clinical research supporting Xyrem®. In Europe, the approval of Xyrem® for the treatment of cataplexy in patients with narcolepsy provides a welcome addition to the pharmacological armamentarium.”

Notes to Editor

1. UCB acquired the licence to distribute Xyrem® in Europe from Orphan Medical recently acquired by Jazz Pharmaceuticals). Xyrem® is marketed in the U.S. by Jazz Pharmaceuticals and has been available in the U.S. since 2002.

2. <u>Orphan medicinal product designation</u>

   Xyrem® was designated as an orphan medicinal product on February 3, 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. European orphan drug designation enables recipient sponsors to receive regulatory guidance in the drug development process and allows for up to 10 years of European market exclusivity for the designated indication upon approval of the market application.

3. <u>Clinical trials</u>

   The European marketing approval of Xyrem® was mainly based on a prospective, multicentre, randomized, double-blind, placebo-controlled trial that examined the safety and efficacy of Xyrem® (3 g, 6 g and 9 g) for the treatment of narcolepsy symptoms. Xyrem® was taken in divided nightly doses immediately before bed-time and repeated 2½-4 hours later. Results of this four-week study showed that in comparison to placebo, Xyrem® demonstrated clinical improvements in the reported number of weekly cataplexy attacks and daytime sleepiness. Investigators assessed changes in disease severity using the Clinical Global Impression of change (CGI-c) measure, and Xyrem® (9 g) was found to significantly decrease the frequency of cataplexy attacks compared to placebo[1].

A follow-up, 12–month open-label study showed that Xyrem® (3-9 g) was well-tolerated and produced significant and long-term clinical improvement in the frequency of cataplexy attacks and diminished day-time sleepiness[3].

About UCB

UCB (www.ucb-group.com) is a global biopharmaceutical leader with headquarters in Brussels, Belgium, specialising in the fields of central nervous system disorders, inflammatory diseases, and oncology. UCB key products are Keppra® (antiepileptic), Xyzal® and Zyrtec® (antiallergics), Nootropil® (cerebral function regulator), Tussionex® (antitussive) and Metadate™ / Equasym XL™ (attention deficit/hyperactivity disorder). UCB employs over 8,500 people operating in over 40 countries. UCB is listed on Euronext Brussels (UCB / UCBBt.BR / UCB BB).

For further information please contact:

Jean-Christophe Donck
Vice President Corporate Communication & Investor Relations
Phone +32 2 559 9588
Fax +32 2 559 9571
Email jc.donck@ucb-group.com

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[1] The U.S. Xyrem® Multicenter Study Group A randomized, double-blind, placebo controlled multi-centre trial comparing the effects of three doses of orally administered sodium oxybate with placebo for the treatment of narcolepsy *Sleep* 2002: 25 (1), 42-49

[2] http://www.sleepfoundation.org/sleeptionary/index.php?id=12&subsection=symptomsaccessed November 6, 2005

[3] The 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