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Press Release

Positive opinion for UCB's Xyrem® for the treatment of cataplexy in adults with narcolepsy

Brussels (Belgium), June 29, 2005 - UCB announces that the European agency, Committee for Medicinal Products for Human Use (CHMP), has adopted a positive opinion recommending to grant a marketing authorisation for Xyrem® (sodium oxybate 500mg/ml oral solution) for treatment of cataplexy in adult patients with narcolepsy. The European Commission (EC) is now reviewing the CHMP's recommendation and UCB expects the marketing authorisation to be granted in the fourth quarter of 2005. When authorised for marketing by the EC, Xyrem® will be the first drug approved for cataplexy in most EU countries.

Narcolepsy is a serious sleep disorder affecting about 200,000 people in the European Union. Cataplexy is a typical symptom of narcolepsy, second in frequency only to excessive daytime sleepiness. Cataplexy is a sudden loss of control over voluntary muscles, triggered by emotions such as amusement, anger, arousal or fear. Severe cataplexy attacks can cause complete postural collapse. Cataplexy places a high burden on affected patients: not only can sudden cataplexy lead to accidents and injuries but it can mean embarrassment and persistent psychosocial distress and thus severely impact patients' quality of life.

"The addition of Xyrem® to therapies available for narcolepsy would be most welcome," comments Adrian Williams, Sleep Centre, St Thomas Hospital, London (UK), "Published results of studies with Xyrem® and feedback from practitioners in the U.S. suggest that control of difficult cataplexy would be possible."

UCB acquired the license to distribute Xyrem® in Europe from Orphan Medical, Inc. (recently acquired by Jazz Pharmaceuticals, Inc.) who has been distributing Xyrem® in the USA since 2002. Since FDA approval, more than 8,000 patients have been treated effectively with Xyrem®.

Clinical trial results

In a prospective, randomized, placebo-controlled multicenter trial, Xyrem® has demonstrated efficacy against cataplexy. Xyrem® reduced cataplexy attacks by up to 69% (p= 0.0016)[1] within 4 weeks. This reduction in cataplexy was clinically meaningful: 80% of patients treated with 9g Xyrem® daily were rated as "much" or "very much improved" by investigators as opposed to 32% of placebo-treated patients (p= 0.0002).[1] Continuation of treatment for 12 months in an open-label extension trial revealed that the results were maintained in long-term treatment with no evidence for development of tolerance.[2] Moreover, abrupt discontinuation of Xyrem® did not result in withdrawal symptoms.[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, allergy and respiratory diseases, immune and inflammatory disorders, as well as 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 and achieved in 2004 revenues of € 2.1 billion (including net sales, royalties, and fees) and an operating profit before amortisation (EBITA) of € 389 million (on a pro-forma IFRS basis including 12 months of Celltech and excluding the Surface Specialties activities, divested in February 2005). UCB is listed on Euronext Brussels with a market capitalization of approximately € 5.8 billion.

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1 The US Xyrem multicenter study group. Sleep 2002 (25):42-49

2 The US Xyrem multicenter study group. Sleep 2003 (26):31-35

3 The US Xyrem multicenter study group. Clin. Toxicol. 2003 (41): 131-135