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Press Release

New European Approval for Xyrem® Provides Significant Advance in the Treatment of Narcolepsy

European Commission Approves Xyrem® for Treatment of Narcolepsy with Cataplexy in Adult Patients

Brussels, Belgium – March 12, 2007 – 06:00 PM (CET): The European Commission has approved Xyrem® (sodium oxybate) for the treatment of narcolepsy with cataplexy in adult patients. This new indication means that Xyrem® is the first and only European Commission-approved medicine for this indication and supports the European Federation of Neurological Sciences guidelines on the management of narcolepsy which recommend Xyrem® as a viable treatment option across the multiple symptoms.[1]

Narcolepsy is a life-long disorder which typically begins with excessive daytime sleepiness during the second and third decades of life, progressing to include disturbed night-time sleep, cataplexy (muscle weakness), sleep paralysis and hypnagogic hallucinations (hallucinations while falling asleep).

'*A large number of patients require the administration of several medicines to control the core symptoms of narcolepsy. With this new approval, Xyrem® offers physicians and a substantial number of patients a single treatment option*.' said Professor Gert Jan Lammers, Neurologist, Leiden University Medical Center, the Netherlands.

In an extensive clinical trial programme, Xyrem® has been shown to:

- Reduce daytime sleepiness[2,3]
- Lower the number of cataplexy attacks[4,5,6]
- Improve night-time sleep quality[7]
- Produce clinically relevant improvement in daytime functioning – an important component of quality of life[8]

Across all studies, which involved more than 700 patients, Xyrem® was well tolerated.[9]

'*The new indication is an important stage in our plans for the development of Xyrem® and demonstrates our ongoing commitment to rare orphan diseases. The multiple symptoms of narcolepsy can profoundly impact patients' quality of life and we are pleased to offer sleep specialists and patients a new treatment option.* ' said Troy Cox, President CNS Operations, UCB.

Last year, UCB announced an extension to its Xyrem® licence agreement with Jazz Pharmaceuticals, Inc., which doubles the number of countries where UCB has commercialisation rights to the drug, and includes rights to Xyrem® in the treatment of fibromyalgia if and when the product is approved for this indication.

About Xyrem® in Europe[8]

Xyrem® is indicated in Europe for the treatment of narcolepsy with cataplexy in adult patients. The most commonly reported adverse drug reactions are dizziness, nausea, and headache, all occurring in 10% to 20% of patients. Other common adverse drug reactions are anorexia, abnormal dreams, confusion, disorientation, nightmares, sleepwalking, depression, sleep disorder, cataplexy, anxiety, middle insomnia, nervousness, sleep paralysis, somnolence, tremor, balance disorder, disturbance in attention, hypoaesthesia, paraesthesia, sedation, blurred vision, hypertension, dyspnoea, snoring, vomiting, upper abdominal pain, diarrhoea, sweating, muscle cramps, arthralgia, enuresis nocturna, urinary incontinence, asthenia, fatigue, feeling drunk, oedema peripheral and fall.

Xyrem® is contraindicated in patients with hypersensitivity to sodium oxybate or to any of the excipients, in patients with succinic semialdehyde dehydrogenase deficiency or in those being treated with opioids or barbiturates. Sodium oxybate is the sodium salt of gamma hydroxybutyrate (GHB), a CNS depressant active substance with well-known abuse potential. Physicians should evaluate patients for a history of drug abuse and follow such patients closely. The combined use of alcohol or any CNS depressant drug with Xyrem® may result in potentiation of the CNS-depressant effects of sodium oxybate. Therefore

patients should be warned against the use of alcohol in conjunction with Xyrem®. Patients may become confused while being treated with Xyrem®. Patients with a previous history of a depressive illness and/or suicide attempt should be monitored especially carefully for the emergence of depressive symptoms. Xyrem® is considered to be unsafe in patients with porphyria.

Xyrem® has the potential to induce respiratory depression. Special caution should be observed in patients with an underlying respiratory disorder. Given the possibility of increasing the risk of respiratory depression, the concomiatant use of benzodiazepeins and Xyrem® should be avoided. The discontinuation effects of Xyrem® have not been systematically evaluated in controlled clinical trials. In some patients, cataplexy may return at a higher frequency on cessation of sodium oxybate therapy, although this may be due to the normal variability of the disease. In rare cases, events such as insomnia, headache, anxiety, dizziness, sleep disorder, somnolence, hallucination and psychotic disorders have been observed after GHB discontinuation.

Please refer to the Xyrem® Summary of Product Characteristics for full prescribing information.

References

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About UCB

Headquartered in Brussels (Belgium), UCB (www.ucb-group.com <http://www.ucb-group.com>) 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 more than 8400 people in over 40 countries, UCB achieved revenue of 2.5 billion euro in 2006. UCB is listed on the Euronext Brussels Exchange and owns 87.6% of Schwarz Pharma.

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