



Release No 255

12 January 2007

Cipralex[®] approved for the treatment of obsessive compulsive disorder (OCD)

Today, Cipralex[®] (escitalopram) has been approved in the EU for the treatment of obsessive compulsive disorder (OCD) by the Swedish Medical Products Agency (MPA) acting as reference member state for the European Union (EU). The approval is based on clinical studies involving more than 750 patients, which demonstrate that Cipralex[®] is an effective and well-tolerated drug in the treatment of OCD with the added benefit of significantly reducing the risk of relapse in OCD patients.

OCD is a chronic, highly debilitating disorder that is characterised by recurrent, distressing thoughts and impulses (obsessions) and/or repetitive behaviours (compulsions).

"OCD is a disabling anxiety disorder for which Cipralex[®] has demonstrated to be an effective and well-tolerated treatment", said Senior Vice President Anders Gersel Pedersen, Head of Development at Lundbeck. "With the approval for the treatment of OCD, Cipralex[®] is now approved for the treatment of all major anxiety indications and depression."

About the clinical studies

Dose finding study

In a double blind placebo controlled study, 458 OCD patients were randomised to either Cipralex[®] at one of the two doses (10mg or 20mg), or 40mg paroxetine or placebo. The duration of the study was 24 weeks with a primary efficacy assessment after 12 weeks (acute treatment).

At week 12 – the primary efficacy endpoint – 20mg Cipralex[®] showed a statistically significant greater improvement in the Yale-Brown Obsessive Compulsive Scale (Y-BOCS) compared to placebo ($p < 0.005$). 10mg Cipralex[®] compared to placebo was ($p = 0.052$). At week 24 dosages of Cipralex[®] 10mg ($p < 0.05$) and 20mg ($p < 0.005$) showed a statistically significant greater improvement in the Yale-Brown Obsessive Compulsive Scale (Y-BOCS) than in the placebo group – as did paroxetine 40mg ($p < 0.05$).



Relapse prevention study

The long-term efficacy was further supported by a relapse prevention study, where 320 patients (intention-to-treat), following treatment with Ciprale[®] for 16 weeks, were randomised to either placebo or Ciprale[®] for a further 24 weeks of double-blind treatment.

The primary endpoint was time to relapse. The result of this primary analysis showed a significant difference in favour of Ciprale[®] ($p < 0.001$). The number of relapses during treatment with Ciprale[®] (23%) was significantly lower compared to the patients in the placebo group (52%) ($p < 0.001$). The risk of relapsing was 2.7 times higher for the placebo group compared to patients treated with Ciprale[®].

About OCD

OCD is a chronic and disabling disorder with lifetime prevalence of around 2-4%. It is estimated that OCD patients represent more than 10% of patients with anxiety disorders.

Symptoms of OCD can vary, and the obsessions can be thoughts that are often very disturbing to the patient and can lead to compulsive behaviour. Examples of compulsions are repetitive behaviours (such as excessive hand washing/cleaning/hoarding/checking) and mental acts (such as counting/repeating words).

The content of this release does not change the Lundbeck Group's previously announced expectations as announced in connection with reporting for the 3rd quarter 2006 financial result.

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Stock exchange release No 255 – 12 January 2007

About Lundbeck

H. Lundbeck A/S is an international pharmaceutical company engaged in the research and development, production, marketing and sale of drugs for the treatment of psychiatric and neurological disorders. In 2005, the company's revenue was DKK 9.1 billion (approximately EUR 1.2 billion or USD 1.5 billion). The number of employees is approximately 5,000 globally. For further information, please visit www.lundbeck.com