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## **Cipralex effective in treating generalised anxiety, social anxiety and panic disorders**

Results from three clinical studies on Cipralex<sup>®</sup> for the treatment of different anxiety disorders were presented today at the annual meeting of the Anxiety Disorders Association of America (ADAA) in Austin, Texas, USA.

The results of one clinical study showed that Cipralex<sup>®</sup> significantly reduced anxiety in patients with generalised anxiety disorder (GAD) when compared with placebo. At the same time results were presented at the meeting showing that Cipralex<sup>®</sup> in another study significantly reduced panic symptoms in patients with panic disorder when compared with placebo. In the third study Cipralex<sup>®</sup> significantly improved symptoms in patients with social anxiety disorder (SAD) compared to placebo.

"I am satisfied with the results from the studies presented at the ADAA conference. This shows that Cipralex<sup>®</sup> has capabilities which may lead to a broader use than with citalopram, for instance in the treatment of generalised anxiety disorders and social anxiety disorders, for which citalopram today is not approved", says Claus Braestrup, Executive Vice President, Research & Development.

### **Cipralex and Generalised Anxiety Disorder (GAD)**

At the ADAA meeting, Duke University researchers presented clinical study results that show Cipralex<sup>®</sup> significantly reduced anxiety symptoms in patients with generalised anxiety disorder when compared with placebo. In the double blind, placebo-controlled study, 257 patients with GAD participated in an 8 week treatment period with either placebo or Cipralex<sup>®</sup> following a one-week, single-blind placebo period. Patients were 18 to 80 years of age.

Measured by the primary evaluation tool, Hamilton Anxiety Scale (HAMA) Cipralex<sup>®</sup> significantly improved anxiety symptoms relative to placebo treatment. Cipralex<sup>®</sup> also showed significant effect when measured by secondary evaluation tools. Patients treated with Cipralex<sup>®</sup> also experienced improvement in quality of life measured by the Quality of Life Questionnaire. Cipralex<sup>®</sup> was also well tolerated; the most common adverse events reported in Cipralex<sup>®</sup> patients were headache, nausea and insomnia.



GAD is characterized by excessive anxiety and worry about very common situations in daily life, for instance going to work or school. It is difficult for the patient to control their worries.

### **Cipralex<sup>®</sup> and Panic Disorder (PA)**

Researchers from the University of California, San Diego, presented at the conference results from a study, which showed that, when compared to placebo, Cipralex<sup>®</sup> significantly reduced symptoms on many different scales.

In the randomised, double blind, placebo-controlled, multi centre study, 247 patients received either placebo or Cipralex<sup>®</sup> for 10 weeks following a two-week, single blind, placebo period. Patients, ranging from 18 to 80 years old, had been diagnosed with panic disorder with or without agoraphobia (phobic anxiety of going about alone or being in large, open places).

The patients treated with Cipralex<sup>®</sup> experienced a significant improvement in their overall status and especially in quality of life as measured by the Modified Sheehan Panic and Anticipatory Anxiety Scale, the Panic and Agoraphobia Scale as well as HAMA, CGI, Patient Global Evaluation, and the Quality of Life Questionnaire. In the study, Cipralex<sup>®</sup> was well tolerated; the rate of discontinuation due to adverse events was comparable in both the Cipralex<sup>®</sup> and placebo groups. The most common adverse events reported by Cipralex<sup>®</sup> treated patients were headache, nausea and insomnia.

Panic disorder is an anxiety disorder characterised by panic attacks, which are brief episodes of intense fear accompanied by multiple physical symptoms such as violent heart beating, heavy perspiring, tremor, shortness of breath, feeling of strangulation, a weight on the chest, nausea, dizziness, sense of unreality and fear of dying. These attacks happen repeatedly and unexpectedly in the absence of any external threat or other mental disorder. About 2.4 million American adults between the ages of 18 and 54 have panic disorder in any given year. Women are twice as likely to suffer from panic disorder as men. Panic disorder can occur with other anxiety disorders, depressive disorders, or substance abuse.

### **Cipralex and Social Anxiety Disorder (SAD)**

In a third study presented at the ADAA meeting, researchers from the University Hospital of Vienna reported that Cipralex<sup>®</sup> demonstrated a significant improvement relative to placebo in treatment of social anxiety disorder.

Following a one-week, single blind placebo period, 358 patients with social anxiety disorder were randomised to 12 weeks treatment with either Cipralex<sup>®</sup> or placebo. With flexible dosing patients could, if needed, be titrated to higher doses after four, six or eight weeks of treatment.



Cipralex<sup>®</sup> was also well tolerated by patients in the study. The most common adverse events reported by patients treated with Cipralex<sup>®</sup> were headache, nausea and insomnia.

Patients treated with Cipralex<sup>®</sup> showed a significant improvement relative to placebo based on the primary measurement tool, the Liebowitz Social Anxiety Scale (LSAS), which measures a patient's level of fear and avoidance of performance and/or social situations. Significantly higher effect was also reached with Cipralex<sup>®</sup> compared to placebo on the secondary assessments, the CGI-S and CGI-I scales, which indicates the severity of a patient's status and the improvement of this status, as well as two of three items on the Sheehan Disability Scale (SDS), which indicate how the patient handles basic everyday life activities, such as work and family life.

Social anxiety disorder is anxiety and fear of new and unknown events, involving contact with other people. People suffering from social anxiety disorder are afraid of acting wrongly or of having an anxiety attack, as this would be embarrassing and humiliating. People therefore avoid exposing themselves to these situations and isolates themselves from the world. Social anxiety disorder is the third most common psychiatric disorder in the United States, after depression and alcohol dependency. It affects about 5.3 million Americans, or about 3.7 percent of people ages 18-54.

The content of this release will have no influence on the Lundbeck Group's result for the year 2002. The company still expects an increase in turnover of 10-12% and an increase in operating profit of 12-15%.

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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 2001, the Company's revenue was DKK 7.7 billion and the number of employees approx. 4,000