



Release No 39

5 February 2001

Lundbeck has submitted the Registration Dossier for Cipralex™ – the trademark for escitalopram – to the Swedish health authorities

H. Lundbeck A/S has today submitted the registration file for escitalopram to the Swedish health authorities. Sweden has been selected as rapporteur country in the Mutual Recognition Process.

The registration file includes data on more than 2000 patients from United States, Canada, the United Kingdom, France, Belgium, Finland, Switzerland, Sweden, Norway, Estonia, and the Netherlands.

Executive Vice President, R & D, Claus Bræstrup says: "Lundbeck has reached an important milestone with the submission of the registration file for escitalopram. It is only three years ago that we decided to develop escitalopram and we are very proud to be able to deliver a very comprehensive file to the Swedish authorities already now".

Cipralex™ has been chosen as the trademark for escitalopram and Lundbeck has submitted applications to the trademark offices in all relevant countries. Cipralex™ – building on the success of Cipramil®/Celexa® – will be used as Lundbeck's global brand name for escitalopram.

The clinical phase III-studies, which constitute the backbone of the registration file, show that esitalopram has clinically relevant and statistically significant effect on depressed patients (Major Depression, DSM IV). The clinical studies have been conducted both with specialists and in primary care settings in collaboration with Forest Laboratories Inc.

The strength of the results is further emphasised by the fact that they are the first positive pivotal placebo-controlled results to be reported from SSRI depression studies in a general practise setting. Lundbeck intends to commence marketing of Cipralex™ in Europe during the second half of 2001.

The content of this release will not influence the Lundbeck Group's expectations for the financial result 2000, which will be presented on 6th March 2001. In this connection the Company will present its financial expectations for year 2001.



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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 diseases. It had consolidated net turnover of DKK 4.2 billion in 1999 and employs approximately 3,000 people.