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New data on Ebixa® for mild to moderate Alzheimer's disease

Preliminary results from two phase III studies investigating Ebixa® (memantine) in the treatment of mild to moderate Alzheimer's disease were today announced by Forest Laboratories, Inc. and H. Lundbeck A/S respectively.

In one of the studies conducted by Forest Laboratories, Inc. the initial results of a US phase III study of memantine as monotherapy in mild to moderate Alzheimer's disease show that the drug demonstrated a statistically significant difference compared with placebo at the study's primary endpoints of cognition and global outcome.

Results from the study show that patients receiving memantine performed significantly better than patients receiving placebo on both primary outcome measures; the Alzheimer's Disease Assessment Scale – cognitive subscale (ADAS-cog) (p=0.003) a measure of cognitive function, and the Clinician's Interview Based Impression of Change – Plus version (CIBIC-plus), a global measure of overall status (p=0.004). Memantine was well tolerated in the study, and memantine patients experienced adverse events at overall rates that were comparable to patients on placebo.

The double-blind, parallel group, placebo-controlled phase III study was designed to evaluate the safety and efficacy of memantine given as monotherapy at a daily dosage of 10 mg BID to patients with mild to moderate Alzheimer's disease. The six-month study was conducted at 42 US centres and included 403 patients with mild to moderate Alzheimer's disease.

"The results of this study are clearly positive and show significant efficacy and tolerability of memantine in mild to moderate Alzheimer's patients. Ebixa® is currently the only approved drug for moderately severe to severe Alzheimer's disease, and these data strengthen our belief that Ebixa® will be helpful also to the many patients suffering from mild to moderate Alzheimer's disease", said Claus Braestrup, President and CEO of Lundbeck.

The preliminary results of a phase III, six month, double-blind study performed in Europe by Lundbeck were also announced today. This trial

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randomised a total of 470 patients with mild to moderate Alzheimer's disease from 65 centres to memantine 10 mg BID or placebo. In the prospectively defined primary analysis, the difference in values for the primary endpoints, the ADAS-cog and the CIBIC-plus, between the two groups was statistically significantly in favour of the memantine treatment group versus the placebo group at multiple time points, while at week 24 although numerical improvement was observed statistical significance was not reached due to higher than expected response in the placebo group. As in the US trial, adverse event rates overall were similar for both the memantine and placebo treatment groups.

"Forest Laboratories, Inc. expects to file with the FDA for a US registration in mild to moderate Alzheimer's disease mid-2004. Lundbeck will now together with its licensor Merz Pharmaceuticals, initiate registration activities in a number of countries and will consult with the European Agency for the Evaluation of Medicinal Products (EMEA) regarding the filing process for Ebixa® in mild to moderate Alzheimer's in the EU", said Senior Vice President Anders Gersel Pedersen, head of Lundbeck's drug development.

The content of this release will have no influence on the Lundbeck Group's expectations for the financial result for 2003, which will be presented on 9 March, 2004.

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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 2002, the Company's revenue was DKK 9.5 billion. The number of employees is approx. 5,600.