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Release No 74

1 August 2002

Lundbeck and Cephalon initiate clinical trial of CEP-1347 for the treatment of Parkinson's disease

H. Lundbeck A/S and Cephalon, Inc. announced today the start of a large North American clinical trial of CEP-1347 in patients with early stage Parkinson's disease. The study expects to enrol approximately 800 patients at up to 65 locations in the United States and Canada.

The study is a randomized, double-blind, placebo-controlled, dose-finding Phase II/III trial in patients with early stage Parkinson's disease. The objective of the study is to determine whether CEP-1347 may be effective in delaying disability due to progression of Parkinson's disease. Patients will be enrolled into the study and each enrolled patient will receive placebo or CEP-1347 for at least two years.

"Initiating this clinical trial represents the achievement of an important milestone for the company," said Dr. Paul Blake, Senior Vice President of Clinical Research and Regulatory Affairs at Cephalon. "CEP-1347 is the first of Cephalon's oral kinase apoptosis inhibitors to reach this advanced stage of clinical development."

Dr. Claus Braestrup, Executive Vice President of Research and Development at Lundbeck said, "This is the largest clinical phase II trial for Lundbeck ever; CEP-1347 is a very important compound in our endeavour to establish a presence within therapies for neurological diseases."

CEP-1347

CEP-1347 is a potent inhibitor of members of the mixed lineage kinase (MLK) family. MLK family members are key participants in the activation of c-Jun N-terminal kinase (JNK), which is thought to underlie neuronal dysfunction and subsequent death. Research at Cephalon and Lundbeck has shown that CEP-1347 enhances the survival of nerve cells that produce dopamine. Additionally, animal models of Parkinson's disease have shown that CEP-1347 protects the dopamine-producing nerve cells in the brain affected by Parkinson's disease.

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Lundbeck and Cephalon are collaborative partners in the development of CEP-1347. Under the terms of the collaboration, Lundbeck holds exclusive commercial rights to the compound in Europe and certain other territories. Cephalon retains exclusive rights to CEP-1347 in the United States. Kyowa Hakko Kogyo Co., Ltd., is Cephalon's partner for commercializing CEP-1347 in the rest of the world.

Parkinson's Study Group

The study is being conducted by the Parkinson's Study Group, a non-profit, cooperative group of Parkinson's disease experts from medical centres in the United States and Canada who are dedicated to improving treatment for persons affected by Parkinson's disease. "There is currently no drug approved for treatment of Parkinson's disease that has been shown to address cell death in the brain either by protecting cells from further deterioration or by regenerating damaged cells," said Ira Shoulson, MD, Professor of Neurology, Pharmacology, Toxicology and Medicine at the University of Rochester and chair of the Parkinson's Study Group. "This large multi-year study will determine if CEP-1347 has the ability to delay disability in Parkinson's disease." Further information on the study can be obtained at www.PDstudy.com.

Parkinson's Disease

According to the National Parkinson's Foundation, more than one million people in the United States are currently afflicted with Parkinson's disease and 60,000 new cases are diagnosed annually. Parkinson's disease is a progressive disorder of the central nervous system caused by the degeneration of nerve cells in an area of the brain called the substantia nigra. These cells produce dopamine, a brain chemical (so called neurotransmitter) important for regulation of movement. The symptoms of the disease appear when the substantia nigra has lost a large number of its dopamine-producing cells. The classical symptoms of Parkinson's disease include, tremor, difficulty in initiating and performing movement, and stiffness of the body. Current treatments for Parkinson's, such as L-dopa or dopamine agonists, are designed to replace the dopamine lost through the degeneration of nerve cells in the substantia nigra. These drugs improve the symptoms of the disease for a short time, but do not slow its progression or halt the death of dopamine-producing nerve cells.

The content of this release will have no influence on the Lundbeck Group's result for 2002. The company still expects an increase in turnover of approx. 20% compared to 2001, while the operating profit still is expected to increase by 20% compared to 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 disorders. In 2001, the Company's revenue was DKK 7.7 billion and the number of employees approx. 4,000

Founded in 1987, Cephalon, Inc. is an international biopharmaceutical company dedicated to the discovery, development and marketing of innovative products to treat sleep and neurological disorders, cancer and pain. Cephalon currently employs approximately 1,200 people in the United States and Europe. U.S. sites include the company's headquarters in West Chester, Pennsylvania, as well as offices and manufacturing facilities in Salt Lake City, Utah. Cephalon's major European offices are located in Guilford, England, and in Maisons-Alfort, France.