Press release 8 February 2005

Arexis obtains orphan drug designation in the EU for novel cystic fibrosis therapy

GOTHENBURG, SWEDEN –8 February 2005 – The Gothenburg-based drug development company Arexis AB today announced that the European Commission has granted orphan drug status for BSSL, the novel human enzyme replacement therapy for treatment of fat malabsorption in patients with cystic fibrosis.

”The orphan drug designation further underlines the positive results in our clinical trials and supports Arexis’ development towards becoming an integrated pharmaceutical company”, says Dr. Lennart Hansson, CEO at Arexis.

In September 2004, Arexis presented successful results from its Phase II clinical trial on enzyme replacement therapy in cystic fibrosis. The study showed a more rapid and fully restored lipid uptake for cystic fibrosis patients when supplemented with the enzyme BSSL (bile salt-stimulated lipase), compared to conventional treatments using pancreas extract from pigs.

The European Committee for Orphan Medicinal Products (COMP) ruled that recombinant human BSSL satisfies the criteria for orphan drug status in the European Union. COMP asserts that even though satisfactory methods of treatment of cystic fibrosis have been authorised, justifications have been provided that the recombinant human BSSL may be of significant benefit to those affected by the condition.

The regulatory authorities in the EU and the US grant orphan drug status to novel, effective treatments in therapy areas with relatively small patient populations. An orphan drug designation grants the holder market exclusivity for up to 10 and 7 years, respectively. According to the report issued by EMEA (European Medicines Agency), cystic fibrosis affects about 1.3 in 10,000 people in the EU. An orphan drug application has been submitted in the US with the objective to obtain orphan drug designation in 2005.

Arexis is planning a dose-finding study and a phase III trial with protocol assistance from regulatory authorities in order to obtain market authorisation approval. The total global market of the enzyme replacement therapy segment is estimated to exceed US$ 1 billion.

Arexis enquiries:
Mats Strömqvist, PhD, Professor and Project Manager, Arexis
Phone: +46 (0)31 749 11 15
Mobile: +46 (0)706 31 00 35
E-mail: mats.stromqvist@arexis.com

Notes to editors:

About Arexis
Arexis is a privately-owned drug development company with an attractive portfolio of projects, ranging in development from pre-clinical to near commercial stages. Arexis focuses on development of drugs to treat metabolic and inflammatory diseases, such as fat mal-absorption, diabetes, atopic dermatitis and rheumatoid arthritis. These are areas with great unmet medical need and largely unknown disease mechanisms. Arexis has a strong intellectual property and technology platform. The company was founded in 1999 and operates in custom-designed laboratories in the newly built Biotech Center in Gothenburg, Sweden. For more information, please visit www.arexis.com.

BSSL
BSSL (bile salt-stimulated lipase) is a naturally occurring enzyme with a key function to degrade a large spectrum of lipids in food. It is present in the mature pancreas and breast milk. For pharmaceutical use, recombinant human BSSL will be manufactured in a cell-culture system.

Cystic fibrosis
From a nutritional perspective, cystic fibrosis is a disease involving fat mal-absorption due to pancreatic dysfunction. Patients suffer deficiencies in production of key digestive enzymes, and as a result fail to make use of important nutrients of their diet. Without treatment they become malnourished, with serious consequences.

Today, fat malabsorption is treated with an enzyme extract from pig pancreas. This extract essentially lacks BSSL activity since the enzyme is destroyed in the manufacturing process. However, this enzyme is vital for efficient lipid absorption. In order to improve the lipid uptake, cystic fibrosis patients need to take large doses of pancreatic extract with each meal. In addition, they need high quantities of vitamin supplements and other medications, for example antibiotics.