Press Release 18 October 2004

AREXIS PRESENTS SUCCESSFUL PHASE II RESULTS OF NOVEL THERAPY FOR CYSTIC FIBROSIS

Improved lipid uptake and reduced need for pancreatic enzyme supplementation in patients with cystic fibrosis

ST LOUIS, MISSOURI – 18 October 2004 – The Gothenburg-based drug development company Arexis AB presented last Friday the results of a successful Phase II clinical trial on their novel human enzyme replacement therapy for treatment of fat malabsorption in patients with cystic fibrosis.

The presentation was made at the 18th Annual North American Cystic Fibrosis Conference in St Louis, Missouri, by Dr. Birgitta Strandvik, principal investigator and Professor in Paediatrics, Sahlgrenska University Hospital in Gothenburg.

Fat malabsorption is a severe problem for most cystic fibrosis patients due to deficiencies in production of key digestive enzymes in the pancreas. As a result, these patients fail to make use of important nutrients in their diet.

“Good nutritional status is of major importance for health and survival in patients with cystic fibrosis”, said Professor Strandvik.

Arexis’ study shows that cystic fibrosis patients with pancreatic insufficiency have a more rapid and efficient lipid uptake when supplemented with the enzyme BSSL (bile salt-stimulated lipase).

The BSSL therapy showed good effect, was well tolerated and proved superior to current treatment. Patients also spontaneously expressed a subjective well-being during the BSSL treatment.

“Available pancreatic enzyme supplements are incomplete in restoring normal fat absorption. The study proved that BSSL added benefits that could not be obtained with current treatments”, said Professor Strandvik.

The results from the new study are conclusive and Arexis will start clinical Phase III studies in a larger number of patients.

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 Biotech Center in Gothenburg, Sweden.

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 malabsorption 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, which leads to a deterioration of their disease. It is generally stated that patients with cystic fibrosis need at least 120 % of the recommended energy intake for healthy individuals. In addition, bacterial colonization of the airways further increases the need for good nutrition.

Today, fat malabsorption is treated with enzyme extracts from pig pancreas. These extracts essentially lack BSSL activity, and many patients do not achieve a normal lipid uptake despite ingestion of large doses of pancreatic extracts with each meal. In addition, patients with cystic fibrosis need to take high doses of vitamin supplements and other medication, for example antibiotics.