

Press release 7 March 2005



Arexis enters into collaboration with CMC Biopharmaceuticals for the production of BSSL for clinical trials

GOTHENBURG, SWEDEN – 7 March 2005 – The drug development company Arexis AB announced today that it has entered into a collaboration agreement with the Danish company CMC Biopharmaceuticals on the production of recombinant human BSSL for the upcoming cystic fibrosis and preterm infant clinical trials.

The collaboration represents an important step in the preparations for the BSSL (bile salt-stimulated lipase) clinical trials in cystic fibrosis patients with fat malabsorption and preterm infants. Under the collaboration agreement, Copenhagen-based CMC Biopharmaceuticals, a contract development and manufacturing organization specialized in GMP manufacturing (good manufacturing practice, required for substances in clinical development), will provide Arexis with all recombinant human BSSL for the trials.

“With its impressive qualities in GMP manufacturing, CMC represents an ideal partner for the timely and reliable delivery of high-quality BSSL for our clinical trials,” says Lennart Hansson, CEO of Arexis.

“Recombinant BSSL is an exciting new biopharmaceutical, and we look forward to starting production in a close and fruitful collaboration with Arexis,” says Mads Laustsen, CEO of CMC Biopharmaceuticals.

The key function of BSSL is to degrade a large spectrum of lipids in food. Arexis’ BSSL program consists of two projects where its patented human recombinant enzyme is used to target fat malabsorption in cystic fibrosis patients and preterm infants. Following the recent successful cystic fibrosis phase II clinical trials which proved the concept, Arexis now plans a dose-finding study followed by a clinical phase III trial. Arexis also plans clinical phase II preterm infant efficacy studies. As a future therapeutic option, BSSL is perhaps the most promising new entry of options to improve fat malabsorption currently in development.

The cystic fibrosis project recently received orphan drug status in the EU. The preterm infant studies will be part of the EARNEST EU-funded program, and orphan drug designations will be applied for in the EU and US.

CMC Biopharmaceuticals will produce BSSL in a mammalian cell bioreactor, with the first batch reserved for the dose-finding cystic fibrosis study and the initial preterm infant clinical phase II studies, and the second batch to be used in the clinical phase III cystic fibrosis trial. Mammalian cell culture production

systems are very well established for producing recombinant therapeutic proteins. CMC Biopharmaceuticals will base its production on one of Arexis' proprietary cell lines.

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Notes to editors:

About Arexis

Arexis is a privately owned drug development company with an attractive portfolio of projects ranging from preclinical to near commercial stages. Arexis focuses on development of drugs to treat metabolic and inflammatory diseases such as fat malabsorption, diabetes, atopic dermatitis and rheumatoid arthritis. These are areas with great unmet medical needs 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 an 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 in their diet. Without treatment, they become malnourished, with serious consequences.

Today fat malabsorption is treated with enzyme extracts from pig pancreas. These extracts essentially lack BSSL activity. However, BSSL is vital for efficient lipid absorption. To improve lipid uptake, cystic fibrosis patients need

to take large doses of pancreatic extract with each meal, in addition to the high quantities of other medications they need in their daily life such as antibiotics and vitamin supplements.

Preterm infants

Infants born at less than 37 weeks of gestational age are considered preterm. Due to immature pancreatic and liver functions, preterm infants have an impaired endogenous capacity for intestinal fat digestion. They have an increased morbidity and mortality rate, often remain small throughout life and are at risk of metabolic, cognitive, social and behavioral problems later in life. One particularly feared complication is necrotizing enterocolitis (NEC), of which there is a significantly increased incidence in formula-fed preterm infants. Optimal nutrition during the neonatal period is vital in order to minimize these health threats.

About CMC Biopharmaceuticals A/S

Based in Copenhagen, Denmark, CMC is a contract development and manufacturing organization for biopharmaceutical products, with sales offices in the UK and US.

CMC specializes in process and analytical development as well as the scale-up and cGMP (current Good Manufacturing Practice) manufacturing of biological active pharmaceutical ingredients for pre-clinical and clinical trials. The facility has also been designed to support the commercial production of these products, including therapeutic proteins and monoclonal antibodies. The company is approved by the European Medicines Agency (EMA) and holds a European Manufacturing Authorization. CMC's competitive strength is centred on its broad range of services and the flexibility it can offer its customers, combined with the extensive expertise of its management and key personnel.