

## **Biovitrum begins Exinalda™ study with cystic fibrosis patients with fat malabsorption**

**Stockholm September 16, 2008 - Biovitrum AB (publ) (STO:BVT) reported today the start of a clinical phase II study with Exinalda™, a candidate drug for the treatment of fat malabsorption. The aim of the study is to document the clinical effect of Exinalda in patients with pancreatic insufficiency as the result of cystic fibrosis. The study comprises 18 patients and is being conducted in Poland and the Netherlands. The results of the study are expected during the first half of 2009.**

Biovitrum develops Exinalda as an enzyme replacement treatment for patients with fat malabsorption due to pancreatic insufficiency as a result of, for example, cystic fibrosis (CF). Exinalda is a biotechnically produced version of a human fat-digesting enzyme (bile salt stimulated lipase; BSSL); an enzyme that these patients lack.

"We are pleased to see our portfolio of specialist projects further mature. We currently have seven specialist drugs on the market and six candidates in our R&D portfolio, including Exinalda. Our strategy focuses on taking candidate drugs all the way to the market and then handling the marketing of these drugs ourselves," says Martin Nicklasson, CEO of Biovitrum.

### **For more information, please contact:**

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### **Facts to the editor**

#### **Fat malabsorption**

Cystic fibrosis (CF) is a hereditary disease characterized by difficulties in breaking down fat due to insufficient pancreatic secretion of the fat digesting enzymes (lipases). The consequences are impaired absorption of fats and a risk of malnutrition and vitamin deficiencies.

According to the Center for Disease Control more than 85 percent of patients with cystic fibrosis suffer from impaired function of the pancreas, resulting in poor absorption of fat that may require lifelong treatment. Datamonitor estimated the number of persons with cystic fibrosis to be about 50,000 globally. The total value of the Market for pancreatic enzyme supplements amounted to about USD 500 million in 2007.

#### **About the clinical phase II study**

The open, explorative study that is now underway aims to study the safety and effect of increased fat absorption of patients with pancreatic insufficiency as a result of cystic fibrosis that are undergoing daily treatment with BSSL. The study comprises 18 patients and will be carried out at 4 CF centers in Poland and the Netherlands.

#### **About Biovitrum**

Biovitrum is a pharmaceutical company with operations in Sweden and in the UK. The company markets a range of specialist pharmaceuticals primarily in the Nordic countries. Using its expertise and experience Biovitrum takes scientific innovation all the way to the market and to specialist indication patients with significant medical need. Research expertise and capabilities include development and production of biotechnology therapeutics, as well as small molecule discovery and development. With revenues of approximately SEK 1.3 billion and around 500 employees, Biovitrum is a significant European specialty pharmaceutical player. Biovitrum's share is listed on the OMX Nordic Exchange in Stockholm. For more information go to [www.biovitrum.com](http://www.biovitrum.com)