

PRESS RELEASE, February 6, 2008

## **Biovitrum and Symphogen have Successfully Completed Phase I Clinical Trial with Recombinant Polyclonal Antibody**

**Biovitrum and Symphogen are developing a recombinant, polyclonal antibody (Sym001) for the treatment of Idiopathic Thrombocytopenic Purpura (ITP) and prophylaxis of rhesus hemolytic disease of the newborn. The phase I clinical trial was initiated in March 2007 and the results from the study show that Sym001 is safe and well tolerated.**

STOCKHOLM, Sweden and COPENHAGEN, Denmark – Biovitrum and Symphogen today announced the completion of a phase I clinical trial to test the safety and tolerability of Sym001 in healthy volunteers. The results from the dose-escalation, placebo-controlled study show that Sym001 is well tolerated.

Sym001 is a recombinant, polyclonal antibody product candidate, comprised of 25 different anti-Rhesus D antibodies. Sym001 is in development for the treatment of Idiopathic/Immune Thrombocytopenic Purpura (ITP) and for Anti RhD Prophylaxis (ADP) of hemolytic disease of the newborn. Symphogen and Biovitrum are jointly developing Sym001 under a co-development and commercialization agreement announced in February 2006.

Further clinical development of Sym001 will now be pursued in both indications.

Martin Nicklasson, CEO of Biovitrum, said, "We are very happy to see this advancement in our project portfolio which presently includes nine projects in the clinic. Our partnership with Symphogen is of great strategic value. It fits well with Biovitrum's long experience and broad knowledge within the area of protein therapeutics and matches perfectly our focus on specialist indications."

"Sym001 is the first ever recombinant polyclonal antibody product to enter human clinical trials. The successful completion of this phase I trial is a very significant milestone for Symphogen", said Kirsten Drejer, CEO of Symphogen. "Symphogen's antibody technology platform offers the opportunity to generate

compositions of recombinant polyclonal antibodies as well as single monoclonal antibodies which opens an exciting avenue for development of antibody therapeutics addressing large and unmet medical needs.”

### **About the Sym001 phase I trial**

Altogether 59 RhD-positive (to support further studies in ITP) and 18 RhD-negative (to support further studies in ADP) healthy male volunteers were enrolled in the double-blind<sup>1</sup>, randomized<sup>2</sup>, placebo-controlled<sup>3</sup>, dose-escalation phase I trial. The study objective was to assess the safety and tolerability of Sym001 following a single intravenous infusion. The trial was conducted at a phase I unit in the United States.

<sup>1</sup>Neither individuals nor researchers know who belongs to the control group and the experimental group during the active phase of the trial.

<sup>2</sup>Volunteers are divided between experimental and control groups at random.

<sup>3</sup>Results will be compared with individuals treated with an agent without any actual medicinal effect; the control group.

### **To the Editor:**

#### **About the Market**

Conventional immunoglobulin products are isolated from the blood of donors, and therefore are subject to potential safety issues due to the risk of disease transmission, relatively low batch to batch consistency, as well as to supply shortages caused by dependence on donor blood availability. Biovitrum’s and Symphogen’s recombinant fully human product Sym001 can be produced in unlimited supply, it carries no known risk of viral or prion transmission and the manufacturing process brings the composition of antibodies under control, qualities that the Companies believe makes it a more attractive therapeutic option for both ITP and ADP.

#### **About Sym001**

Sym001 is a recombinant polyclonal composition of 25 different anti-Rhesus D antibodies for the treatment of Idiopathic Thrombocytopenic Purpura and for Anti RhD Prevention of hemolytic disease of the newborn. Preclinical studies of Sym001 demonstrated its binding potency and biological function similar to existing plasma-derived anti-RhD products.

Idiopathic Thrombocytopenic Purpura is an autoimmune bleeding disorder characterized by abnormally low platelet levels, making it difficult for the blood to clot normally. Hemolytic disease of the newborn occurs when an RhD-negative woman becomes sensitized to RhD when carrying an RhD-positive child. This immune reaction can trigger a maternal antibody response in subsequent RhD-positive pregnancies, causing the breakdown of fetal red blood cells, i. e. hemolytic disease.

### **About Biovitrum**

Biovitrum is one of the largest biopharma companies in Europe. With operations in Sweden and in the UK Biovitrum conducts research and develops pharmaceuticals for unmet medical needs both for conditions that affect smaller patient populations and for common diseases. Biovitrum has currently a broad and balanced R&D portfolio with several projects in clinical and preclinical phases for a number of well defined specialist indications as well as for common diseases within obesity, diabetes, inflammation, eye and blood diseases. Biovitrum develops and produces protein-based drugs on a contractual basis and markets a range of specialist pharmaceuticals primarily in the Nordic countries. Biovitrum has revenues of approximately SEK 1.2 billion and around 500 employees. Biovitrum's share is listed on the OMX Nordic Exchange in Stockholm since September 15, 2006. For more information see [www.biovitrum.com/ <http://www.biovitrum.com/>](http://www.biovitrum.com/) .

### **About Symphogen**

Symphogen is the leader in developing recombinant polyclonal antibodies (pAb), a new class of biopharmaceuticals for the treatment of serious human diseases. By employing its pioneering antibody discovery and manufacturing technologies, Symphogen generates recombinant antibody compositions that capture the diversity and effectiveness of the natural immune system. Symphogen is building a proprietary product pipeline within several disease areas, including infectious diseases and cancer. Symphogen has established collaborations with international pharmaceutical companies.

Symphogen is a private biopharmaceutical company with over 80 employees, based in Copenhagen, Denmark. Refer to [www.symphogen.com <http://www.symphogen.com/>](http://www.symphogen.com/) for further information on Symphogen.

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