



## **Symphogen and Swedish Orphan Biovitrum receive U.S. orphan drug designation for Rozrolimupab in ITP**

**Copenhagen, Denmark and Stockholm, Sweden – October 6, 2010** – Symphogen and Swedish Orphan Biovitrum (STO:SOBI) today announced that the United States Food and Drug Administration (FDA) has granted orphan drug designation to rozrolimupab (Sym001) for the treatment of primary Immune Thrombocytopenia (ITP).

An FDA Orphan Drug designation provides tax benefits and an exemption from user fees, eligibility for grant funding, the opportunity of protocol assistance, the possibility to receive a fast track and expedited review process, as well as a seven-year period of market exclusivity after product approval.

ITP is an autoimmune bleeding disorder characterized by abnormally low platelet levels, making it difficult for the blood to clot normally.

“Orphan drug designation provides us with valuable regulatory support for the development of Sym001 in ITP that will be beneficial in our ambition to develop this innovative treatment for chronic ITP patients and provide an alternative treatment to them,” says Peter Edman, Chief Scientific Officer, Swedish Orphan Biovitrum.

“Sym001 is the first ever recombinant polyclonal antibody product to have entered human clinical trials,” stated Kirsten Drejer, PhD., Chief Executive Officer of Symphogen. “Sym001 is currently being studied in a Phase II dose finding trial. We intend to develop it as an alternative to plasma derived anti D and immunoglobulins”.

### **About primary immune thrombocytopenia (ITP)**

Primary Immune Thrombocytopenia (previously called Idiopathic Thrombocytopenic Purpura) (ITP) is a rare, chronic and debilitating autoimmune disorder associated with increased bleeding risk and impaired quality of life. The primary cause of long-term morbidity and mortality in patients with ITP is hemorrhage<sup>1</sup>. The prevalence of ITP in the United States is estimated to be 34,200.

<sup>1</sup>Danese MD et al. Cost and mortality associated with hospitalizations in patients with immune thrombocytopenic purpura. *Am J Hematol.* Jul 16 2009.

### **About Sym001**

Rozrolimupab (Sym001) is a recombinant polyclonal composition of 25 different Rhesus D specific antibodies for the treatment of primary Immune Thrombocytopenia (formerly designated Idiopathic Thrombocytopenic Purpura) (ITP) and for Anti-RhD prophylaxis (ADP) in prevention of Hemolytic Disease of the Newborn. In February 2008, Symphogen and Biovitrum reported results from a Phase I dose-escalation, placebo-controlled trial, demonstrating that Sym001 was safe and well tolerated. In November 2008 Symphogen and Biovitrum reported the results of a clinical study which demonstrated proof of concept in healthy volunteers. The results showed that Sym001 cleared the RhD-positive red blood cells and that the clearance was dose dependent. The ongoing phase II clinical trial evaluates the safety and efficacy, and explores the dose range of Sym001 in immune thrombocytopenia patients.

### **About Symphogen**

Symphogen is developing superior antibody therapeutics (monoclonal, monoclonal mixtures and polyclonal) to help people with serious diseases and significant unmet medical needs. With its proprietary, unique Symplex™ discovery and Sympress™ manufacturing platforms, the company captures the diversity and specificity of the natural immune response in rationally designed recombinant antibody compositions. Symphogen is maturing a diversified pipeline of internal and partnered products across multiple indications including cancer, autoimmune and infectious disease. Symphogen is a private biopharmaceutical company headquartered in Copenhagen, Denmark, with a US subsidiary in Princeton, New Jersey.

### **About Swedish Orphan Biovitrum**

Swedish Orphan Biovitrum is a Swedish based niche specialty pharmaceutical company with an international market presence. The company is focused on providing and developing specialist pharmaceuticals for rare disease patients

with high medical needs. The portfolio consists of about 60 marketed products and an emerging late stage clinical development pipe-line. Our focus areas are: hemophilia, inflammation/autoimmune diseases, fat malabsorption, cancer supportive care and inherited metabolic disorders. Swedish Orphan Biovitrum had pro-forma revenues 2009e of about 2 BSEK and approximately 500 employees. The head office is located in Sweden and the share (STO: SOBI) is listed on NASDAQ OMX Stockholm. For more information please visit [www.sobi.com](http://www.sobi.com).

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*Swedish Orphan Biovitrum may be required to disclose the information provided herein pursuant to the Swedish Securities Markets Act. The information was provided for public release on October 6, 2010 at 8:30 a.m. CET.*