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Biovitrum and Symphogen Report Positive Clinical Results in Novel Rh-immunization Prevention Project

STOCKHOLM, Sweden and COPENHAGEN, Denmark – November 20, 2008. Biovitrum AB (publ) (STO:BVT) and Symphogen A/S have completed the first part of a clinical proof of mechanism study of the recombinant human polyclonal antibody product Sym001 for future prevention of Hemolytic Disease of the Newborn (HDN) that can occur in RhD-negative mothers carrying a RhD-positive fetus. This can lead to an immune reaction causing destruction of the red blood cells in the newborn, which may give rise to severe anemia, jaundice, and even cause heart failure and fatality.

This part of the first clinical study investigated the ability of Sym001 to clear RhD-positive red blood cells given intravenously to 24 RhD-negative healthy males. Positive control was the plasma-derived product Rhophylac®, given to 12 subjects. The preliminary results demonstrate that the recombinant human polyclonal antibody product is able to clear RhD-positive blood cells at five days after dosing in a dose dependent manner.

Biovitrum and Symphogen are now planning for the next step of the clinical programme which should lead to a decision to initiate phase III studies in the intended label population, namely Rh-negative mothers carrying an Rh-positive fetus

"Clearance of RhD-positive red blood cells from the circulation is key for the prevention of HDN and thereby constitutes a significant medical need. It is therefore with great satisfaction we note these positive results which advances the development of this innovative biotechnology therapy to prevent newborns from developing HDN.", said Martin Nicklasson, CEO of Biovitrum.

"Sym001 is the first ever recombinant human polyclonal antibody product to have entered human clinical trials and this red blood cell challenge study is an important step in the further development of Sym001", said Kirsten Drejer, CEO of Symphogen. "Symphogen's antibody technology platform offers the opportunity to generate compositions of recombinant human polyclonal antibodies as well as single monoclonal antibodies which opens an exciting avenue for development of antibody therapeutics addressing unmet medical needs."

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To the Editor:

About the Sym001 red blood cell challenge study
The results show that Sym001 cleared the RhD-positive red blood cells and that the clearance is dose dependent. At the highest dose level of Sym001 studied (900 µg) the clearance at five days after dosing (primary end-point) was comparable to that of Rhophylac®. Sym001 was found to be safe and well-tolerated at all doses studied.

The study included 24 subjects at three dose levels of Sym001 and 12 subjects given 300 µg Rhophylac®. The study was carried out at a single center in Berlin.

The study was a dose-adjusting, randomized[1] and partly double-blind[2] clinical trial. Sym001 was compared with an active control[3]. The primary objective was to study the ability of Sym001 to clear RhD-positive red blood cells, following their administration to RhD-negative healthy subjects (so-called RBC challenge[4]) as a model for Anti-D prophylaxis.

The full trial comprises two parts: In the first part (just completed with interim results presented above) Sym001 or control was administered intravenously to a 36 healthy male subjects. In the second part administration is planned to be done intramuscularly to a maximum of 30 healthy male subjects. The trial is conducted at a clinic in Germany.

[1]Volunteers are divided between experimental and control groups at random
[2]Neither individuals nor researchers know who belongs to the control group and the experimental group during the active phase of the trial..
[3]Results will be compared with individuals treated with an active agent with the desired effect on RhD-positive red blood cells.
[4]Administration of RhD-positive red blood cells aimed at provoking an immune response, i.e. generation of anti-D antibodies.

About Anti- D Prophylaxis (ADP) and Hemolytic Disease of the Newborn (HDN)
HDN occurs when an RhD-negative woman becomes sensitized to RhD when carrying an RhD-positive fetus. This immune reaction can trigger a maternal antibody response in subsequent RhD-positive pregnancies, causing the breakdown of fetal red blood cells in the newborn, i. e. hemolytic disease. Anti-D prophylaxis (ADP) means prevention of such maternal antibody response by administration of anti-D products (Rh-immunization) which clear fetus's RBC before they trigger sensitization of the maternal immune system.

About Sym001

This novel intervention does not carry with it the risks of current immunoglobulin therapies related to their blood donor origin. Symphogen and Biovitrum are jointly developing Sym001 under a co-development and commercialization agreement. A phase 1 clinical study completed in February 2008 showed that Sym001 is safe and well tolerated in healthy volunteers.

Sym001 is a human recombinant polyclonal composition of 25 different human IgG1 (Rhesus-D specific) antibodies for anti-RhD prevention of Hemolytic Disease of the Newborn and for the treatment of Immune Thrombocytopenic Purpura. Preclinical studies of Sym001 demonstrated a binding potency and biological function similar to existing plasma-derived anti-RhD products. A phase 1 clinical trial was completed in February 2008 and the results showed that Sym001 is safe and well tolerated in healthy volunteers.

About the Market

Conventional immunoglobulin products are isolated from the blood of donors. They 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 dependency on donor blood availability. Biovitrum's and Symphogen's recombinant human polyclonal antibody 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, product qualities which the Companies believe makes it a more attractive therapeutic option for both ITP and ADP.

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

About Symphogen

Symphogen is the leader in developing recombinant humanpolyclonal 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 employing 85 people, based in Copenhagen, Denmark. Refer to www.symphogen.com for further information on Symphogen.