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Biovitrum and Syntonix set to begin phase I/IIa clinical trial of long-acting recombinant Factor IXFc for the treatment of Hemophilia B

Biovitrum AB (publ), Sweden, and Syntonix Pharmaceuticals, Inc., USA, have obtained approval from the US Food and Drug Administration to commence a clinical phase I/IIa study of a long-acting, recombinant Factor IXFc for the treatment of Hemophilia B.

The US Food and Drug Administration (FDA) has approved the initiation of a phase I/IIa safety and pharmacokinetic study of intravenous, long-acting, recombinant Factor IX (FIXFc) in previously treated hemophilia B patients. This first in human study aims to evaluate the safety and tolerability of FIXFc together with its pharmacokinetic profile (primarily its plasma half-life) after a single injection of six different doses. The study will be performed at two clinics in the United States.

There is an increasing trend toward use of Factor IX for prophylaxis treatment of Hemophilia B, which requires several infusions per week with the currently available drugs. The extended half-life of this new FIXFc product could enable effective treatment for both prophylaxis and on-demand therapy with less frequent intravenous injections and thereby provide a new, improved therapy for the patients. The total market potential for Factor IX products is estimated to be in excess of USD 600 million worldwide, per year.

"Hemophilia is a prioritized therapeutic and business area within Biovitrum. We are excited to develop FIXFc with Syntonix because we believe that the company's' SynFusion™ technology has resulted in a very promising, long-acting recombinant Factor IX product opportunity that has the potential to reduce the frequency of infusions required for Hemophilia B patients to manage their disease. The program fits well with Biovitrum's long experience and broad knowledge within the area of protein therapeutics and matches perfectly our focus on specialist indications." said Martin Nicklasson, CEO of Biovitrum.

About Hemophilia
Hemophilia is a rare hereditary disorder in which the ability of patients' blood to clot is impaired. As a result, the patient suffers from excessive bleeding and uncontrolled internal bleeding, leading to pain and eventual permanent damage to joints and muscles. One form, Hemophilia B results from mutations that impair the production of Factor IX. It has been reported that even with "proper treatment" the life expectancy of hemophilia patients is about 10 years less than for individuals without hemophilia. Increasingly, the normal mode of treatment for younger patients is a prophylaxis regimen where patients are infused two or three times per week to maintain a better circulating level of coagulation factor. Long term studies demonstrate that such regimens greatly reduce if not eliminate progressive joint deterioration.

About Biovitrum
Biovitrum is a pharmaceutical company with operations in Sweden and in the UK. Biovitrum has currently a research 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 and eye 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/.

About Syntonix
Syntonix Pharmaceuticals, Inc. (Waltham, MA, USA) is a wholly-owned subsidiary of Biogen Idec. Syntonix is developing next generation biopharmaceuticals that enable better treatment options for patients with devastating chronic diseases such as hemophilia and autoimmune disorders. The company applies its core technologies to develop long-acting biopharmaceuticals that may be injected less frequently, and to discover novel drugs to treat antibody-mediated autoimmune and inflammatory disorders. The resulting proteins, peptides and antibodies are being commercialized through internal development programs and collaborations with biotechnology and pharmaceutical partners. More information is available at http://www.syntnx.com/.

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