



## Biogen Idec and Swedish Orphan Biovitrum Receive Opinion from EMA on Pediatric Plan for Long-Lasting Hemophilia B Therapy

May 9, 2011

WESTON, Mass. & STOCKHOLM--([BUSINESS WIRE](#))--[Biogen Idec](#) (NASDAQ: BIIB) and Swedish Orphan Biovitrum (STO: SOBI) today announced that the European Medicines Agency's (EMA) Pediatric Committee (PDCO) has adopted an opinion agreeing to the pediatric investigational plan for the companies' long-lasting, fully-recombinant Factor IX Fc fusion protein (rFIXFc).

In accordance with the PDCO's opinion, Biogen Idec and Swedish Orphan Biovitrum plan to initiate a global pediatric trial in previously-treated patients under 12 years of age as soon as sufficient data are available from a study of older patients. Under draft guidelines published by the EMA for the development of Factor IX products, pediatric data from this trial will be required in the initial submission of a Marketing Authorization Application to the European regulatory agency.

"The EMA's agreement to our pediatric investigational plan is another milestone in our effort to develop innovative therapies for people with hemophilia," said Glenn Pierce, M.D., Ph.D., Senior Vice President of Hemophilia at Biogen Idec. "With this opinion and the ongoing Phase 3 trials of our long-lasting Factor IX and Factor VIII programs, we continue to make progress toward our goal of improving the way hemophilia is treated worldwide."

"The opinion from the EMA's Pediatric Committee is valuable for our promising rFIXFc project, as it allows for the development of rFIXFc in the pediatric population. We are excited about the potential of this innovative product to make a difference in the lives of people with hemophilia," said Peter Edman, Ph.D., Chief Scientific Officer of Swedish Orphan Biovitrum.

### About rFIXFc and the recombinant Fc Fusion protein hemophilia program

rFIXFc is a recombinant Factor IX Fc fusion protein developed using monomeric Fc fusion technology. The technology makes use of a natural mechanism that recycles rFIXFc in the circulation to extend its half-life. It is a fully-recombinant clotting factor designed to replace the protein that hemophilia B patients lack and to last longer in the body than commercially-available Factor IX products. rFIXFc is currently being evaluated in a registrational, open-label, multicenter trial (B-LONG) designed to evaluate its safety, pharmacokinetics and efficacy in hemophilia B patients.

Using the same proprietary monomeric Fc fusion technology as rFIXFc, Biogen Idec and Swedish Orphan Biovitrum are also developing a fully-recombinant, long-lasting Factor VIII Fc fusion protein (rFVIII Fc) for the treatment of hemophilia A. rFVIII Fc is currently being evaluated in a registrational, open-label, multicenter trial (A-LONG) designed to evaluate its safety, pharmacokinetics and efficacy in hemophilia A patients. For more information on the rFIXFc and rFVIII Fc trials, please visit [www.biogenidechemophilia.com](http://www.biogenidechemophilia.com) or [www.clinicaltrials.gov](http://www.clinicaltrials.gov).

### About Hemophilia B

Hemophilia B is a rare, inherited disorder in which the ability of a person's blood to clot is impaired. Hemophilia B occurs in about one in 25,000 male births annually and is caused by having substantially reduced or no Factor IX protein, which is needed for normal blood clotting. People with hemophilia B therefore need injections of Factor IX to restore the coagulation process and prevent frequent bleeds that could otherwise lead to pain, irreversible joint damage and life-threatening hemorrhages. Prophylactic treatment with infusions twice per week to maintain a sufficient circulating level of coagulation factor is being increasingly used, and long-term studies demonstrate that such regimens increase the patient's life expectancy and greatly reduce, if not eliminate, progressive joint deterioration.

### About Biogen Idec

Biogen Idec uses cutting-edge science to discover, develop, manufacture and market therapies for serious diseases with a focus on neurology, immunology and hemophilia. Founded in 1978, Biogen Idec is the world's oldest independent biotechnology company. Patients worldwide benefit from its leading multiple sclerosis therapies, and the company generates more than \$4 billion in annual revenues. For product labeling, press releases and additional information about the company, please visit [www.biogenidec.com](http://www.biogenidec.com).

### About Swedish Orphan Biovitrum (Sobi)

Sobi 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 pipeline. Our focus areas are: hemophilia, inflammation/autoimmune diseases, fat malabsorption, cancer and inherited metabolic disorders. Sobi 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).

### Safe Harbor

This press release contains forward-looking statements, including statements about the development of long-lasting hemophilia therapies. These statements may be identified by words such as "believe," "expect," "may," "plan," "will" and similar expressions, and are based on the companies' current beliefs and expectation. Drug development involves a high degree of risk. Factors which could cause actual results to differ materially from the companies' current expectations include the risk that we may not fully enroll our planned clinical trials, unexpected concerns may arise from additional data or analysis, regulatory authorities may require additional information, further studies, or may fail to approve the drug, or the companies may encounter other unexpected hurdles. For more detailed information on the risks and uncertainties associated with Biogen Idec's drug development and other activities, see the periodic reports of Biogen Idec filed with the Securities and Exchange Commission. Any forward-looking statements speak only as of the date of this press release and the companies assume no obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise.

*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 May 9, 2011, 11:00 a.m. CET.*

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