



## Biogen Idec and Sobi Present New Data from the Phase 3 Study of Their Long-Lasting Hemophilia Factor Candidate ALPROLIX™

July 2, 2013

### ***Additional B-LONG Study Results Support Positive Clinical Profile of ALPROLIX for Hemophilia B***

WESTON, Mass. and STOCKHOLM--([BUSINESS WIRE](#))--[Biogen Idec](#) (NASDAQ: BIIB) and Swedish Orphan Biovitrum AB (publ) (Sobi) (STO: SOBI) today presented new findings for their long-lasting recombinant factor IX candidate ALPROLIX<sup>®</sup> for hemophilia B at the XXIV International Society on Thrombosis and Haemostasis (ISTH) Congress in Amsterdam, The Netherlands. Three oral presentations showcase new data that reinforce the potential safety, efficacy and pharmacokinetic profile of ALPROLIX. The data highlight the consistency of results with ALPROLIX across patient types and favorable physician ratings of its efficacy in treating acute bleeding episodes and controlling bleeding during and after major surgery.

"ALPROLIX is the first product candidate in a new class of long-lasting clotting factor therapies, and the data presented today support the potential of the therapy to reduce the frequency of prophylactic infusions for patients with hemophilia B," said Glenn Pierce, M.D., Ph.D., senior vice president of Global Medical Affairs and chief medical officer of Biogen Idec's hemophilia therapeutic area. "These new data help to build the clinical profile of ALPROLIX by increasing our understanding of its efficacy."

#### **Treatment of Bleeding**

An evaluation of the treatment of acute bleeding episodes across the prophylaxis and episodic (on-demand) treatment arms of the phase 3 B-LONG study showed that more than 90% of bleeds were controlled with a single injection of ALPROLIX and more than 97% were controlled with two or fewer injections. These data were showcased in the e-poster presentation:

- *Treatment of Bleeding Episodes in Subjects with Haemophilia B with the Long-Lasting Recombinant Factor IX Fc Fusion Protein (rFIXFc) in the Phase 3 B-LONG Study*

#### **Surgery Analysis**

Results from an analysis of the phase 3 B-LONG study showed that ALPROLIX consistently controlled bleeding during and after 14 major surgeries in 12 patients with hemophilia B. Physicians reported high efficacy levels of ALPROLIX during surgery, with hemostasis (the stoppage of bleeding) rated as "excellent" for 13/14 surgeries and "good" for 1/14 surgeries. According to investigator analyses, the results were comparable to that for similar surgeries in people without hemophilia. These data were showcased in the e-poster presentation:

- *Long-Lasting Recombinant Factor IX Fc Fusion (rFIXFc) for Perioperative Management of Subjects with Haemophilia B in the Phase 3 B-LONG Study*

#### **Population Pharmacokinetics (PK) Analysis**

Analysis of a population pharmacokinetics (popPK) model developed for ALPROLIX demonstrated that the model accurately predicts peak and trough factor IX activity levels achieved in the B-LONG clinical study at a variety of ALPROLIX doses. These data were showcased in the e-poster presentation:

- *Clinical Implications of Population Pharmacokinetics of rFIXFc in Routine Prophylaxis, Control of Bleeding and Perioperative Management for Haemophilia B Patients*

"These new data from the B-LONG study support the potential application of Fc fusion technology in hemophilia," said Birgitte Volck, M.D., Ph.D., senior vice president development and chief medical officer of Sobi. "The results add to the growing body of evidence supporting the potential efficacy and safety of this long-lasting clotting factor candidate for the treatment of hemophilia B."

#### **ALPROLIX Global Regulatory Status**

A Biologics License Application (BLA) for Biogen Idec's long-lasting hemophilia product candidate ALPROLIX is currently under review with the U.S. Food and Drug Administration (FDA) for the treatment of hemophilia B.

Marketing Applications for ALPROLIX have been submitted in Canada and Australia for the treatment of hemophilia B. Additional regulatory filings are planned.

#### **About the Fc Fusion Technology Platform**

ALPROLIX is a clotting factor under development using Biogen Idec's novel and proprietary monomeric Fc fusion technology, which makes use of a naturally occurring pathway that delays the breakdown of factor in the body and cycles it back into the bloodstream, resulting in a longer circulating half-life. Fc fusion technology is used in seven FDA-approved products for the treatment of chronic diseases including rheumatoid arthritis, psoriasis and platelet disorders. Biogen Idec is the first and only to apply this proprietary technology to hemophilia.

#### **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 activity, which is needed for normal blood clotting. People with hemophilia B experience bleeding episodes that can cause pain, irreversible joint damage and life-threatening hemorrhage. Injections of factor IX can restore the

coagulation process, control bleeding, and prevent new bleeding episodes. The Medical and Scientific Advisory Council of the National Hemophilia Foundation recommends prophylaxis as the optimal therapy for people with severe hemophilia B. According to the World Federation of Hemophilia, prophylaxis in hemophilia B typically requires injections up to three times per week to maintain a sufficient circulating level of clotting factor.

### **About the Biogen Idec and Sobi Collaboration**

Biogen Idec and Swedish Orphan Biovitrum (Sobi) are partners in the development and commercialization of ELOCTATE in hemophilia A and ALPROLIX in hemophilia B. Biogen Idec leads development, has manufacturing rights, and has commercialization rights in North America and all other regions excluding the Sobi territory. Sobi has the right to opt in to assume final development and commercialization in Europe (including Russia), the Middle East and Northern Africa.

### **About Biogen Idec**

Through cutting-edge science and medicine, Biogen Idec discovers, develops and delivers to patients worldwide innovative therapies for the treatment of neurodegenerative diseases, hemophilia and autoimmune disorders. 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 \$5 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 Sobi**

Sobi is an international specialty healthcare company dedicated to rare diseases. Our mission is to develop and deliver innovative therapies and services to improve the lives of patients. The product portfolio is primarily focused on inflammation and genetic diseases, with three late stage biological development projects within hemophilia and neonatology. We also market a portfolio of specialty and rare disease products for partner companies. Sobi is a pioneer in biotechnology with world-class capabilities in protein biochemistry and biologics manufacturing. In 2012, Sobi had total revenues of SEK 1.9 billion (€ 215 M) and about 500 employees. The share (STO: SOBI) is listed on NASDAQ OMX Stockholm. More information is available at [www.sobi.com](http://www.sobi.com).

### **Biogen Idec Safe Harbor**

This press release contains forward-looking statements, including statements about the potential impact and therapeutic effect of our long-lasting hemophilia product candidates and regulatory filings. These statements may be identified by words such as "believe," "expect," "may," "plan," "potential," "will" and similar expressions, and are based on our current beliefs and expectations. Drug development and commercialization involve a high degree of risk. Factors which could cause actual results to differ materially from our current expectations include the risk that unexpected concerns may arise from additional data or analysis, regulatory authorities may require additional information or further studies, or may fail to approve or may delay approval of our drug candidates, or we may encounter other unexpected hurdles. For more detailed information on the risks and uncertainties associated with our drug development and commercialization activities, please review the Risk Factors section of our most recent annual or quarterly report filed with the Securities and Exchange Commission. Any forward-looking statements speak only as of the date of this press release and we assume no obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise.

*\*ALPROLIX<sup>TM</sup> Coagulation Factor IX (Recombinant Fc Fusion Protein)*

### **Multimedia Files:**

[Download All Files](#)

 [Preview image](#)

Download:

[Download ViewImage](#) (11.94 KB)

[Download High Resolution](#) (71.05 KB)

[Download Thumbnail](#) (6.34 KB)

[Download Square](#) (11.88 KB)

[Download Web Ready](#) (43.83 KB)

### **Contact:**

BIOGEN IDEC CONTACT:

Media Contact:

Todd Cooper, +1-781-464-3260

Senior Director, Public Affairs

or

Investor Relations Contact:

Ben Strain, +1-781-464-2442

Senior Manager, Investor Relations

or

SWEDISH ORPHAN BIOVITRUM CONTACT:

Media Contact:

Oskar Bosson, +46 70 410 71 80

Head of Communications

or

Analyst/Investor Contact:

Jörgen Winroth, +46 8 697 20 00

Vice President, Head of Investor Relations