

PRESS RELEASE

Stockholm, Sweden 30 January, 2015

Xiapex approved by the EU Commission for the treatment of Peyronie's disease

[Swedish Orphan Biovitrum AB \(publ\)](#) (Sobi) today announced that the EU Commission has approved Xiapex® (collagenase clostridium histolyticum) for the treatment of adult men with Peyronie's disease with a palpable plaque and curvature deformity of at least 30 degrees at the start of therapy. Peyronie's disease is a condition that involves the development of collagen plaque, or scar tissue, on the shaft of the penis.

"We are very pleased with the approval by the EU Commission and that we are now able to expand the treatment options for patients with Peyronie's Disease. Patients with severe symptoms of their disease, both physical and psychological, can now be offered a therapeutic alternative to surgical intervention," says Birgitte Volck, Senior Vice President & Chief Medical Officer at Sobi.

Xiapex was approved in December 2013 by the Food and Drug Administration (FDA) in the United States for the treatment of Peyronie's disease with a palpable plaque and curvature deformity of at least 30 degrees at the start of therapy. Xiaflex® (collagenase clostridium histolyticum) is the trade name for Xiapex used in the United States.

Xiapex is also approved in the European Union (EU) for the treatment of Dupuytren's contracture in adult patients with a palpable cord. In 2013 Sobi and Auxilium Pharmaceuticals Inc. signed an agreement giving Sobi the exclusive rights to commercialise Xiapex for the treatment of Dupuytren's contracture and Peyronie's disease in 71 Eurasian and African countries. Sobi is Marketing Authorisation Holder (MAH) for Xiapex in the 28 EU Member States, as well as Norway and Iceland.

About Peyronie's disease

Peyronie's Disease (PD) is a condition that involves the development of collagen plaque, or scar tissue, on the shaft of the penis. The scar tissue, known as a Peyronie's plaque, may harden and reduce flexibility, which may cause bending or arching of the penis during erection. PD can result in varying degrees of penile curvature deformity and disease "bother" (encompassing concern about erection appearance, erection pain and the impact of PD on intercourse and on frequency of intercourse). PD is a disease with an initial inflammatory component. This inflammatory phase is poorly understood with a somewhat variable disease course and spontaneous resolution occurring in less than 13 percent of casesⁱ. After approximately 12 months of disease, the disease is reported to often develop into a more chronic, stable phaseⁱ. The incidence of PD is estimated between 3 and 9 percentⁱⁱ; however the disease is thought to be underdiagnosed and undertreatedⁱ.

About Xiapex

Xiapex (collagenase clostridium histolyticum), is a pharmacological treatment for Peyronie's disease and Dupuytren's contracture and may be an alternative to invasive and often complicated surgery for patients. Xiapex is a combination of two purified clostridial collagenases for injection that enzymatically disrupts the contracting cord and collagen plaque and reduces the contraction. Xiapex is administered by local injection directly into the Dupuytren's cord in the finger or in the plaque on penis. Twenty-four hours after the injection, a finger extension procedure can be carried out as necessary to break the cord and allow extension of the Dupuytren's

Swedish Orphan Biovitrum AB

Postal address SE-112 76 Stockholm, Sweden

Phone: +46 8 697 20 00 Fax +46 8 697 20 00 www.sobi.com

affected finger. As a complement to Xiapex injection treatment for Peyronie’s disease, modelling of the penis is needed. Modelling is performed 24-72 hours after the second injection of the cycle in an attempt to further disrupt the plaque and help straighten the penis.

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 two late-stage biological development projects within Haemophilia. 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 2013, Sobi had total revenues of SEK 2.2 billion (€253 M) and about 550 employees. The share (STO: SOBI) is listed on NASDAQ OMX Stockholm. More information is available at www.sobi.com.

About Sobi Partner Products

Sobi Partner Products (SPP) is a business unit within Sobi that offers a unique commercial platform for partners with niche and specialty products. SPP provides extensive knowledge and local experience through our direct presence across EU, Eastern Europe, Russia, Middle East and North Africa. We apply an integrated commercial, medical and market access approach to products that address important unmet needs, spanning from named patient use (NPU) programmes, through to reimbursement and full commercialisation, primarily in the Centre of Expertise setting.

For more information please contact

Sobi contacts:

Media relations

Charlotte af Klercker

Senior Communications Manager

+46 70 729 73 27

Charlotte.afklercker@sobi.com

Investor relations

Jörgen Winroth

Vice President, Head of Investor Relations

+1 347-224-0819, +1 212-579-0506, +46 8 697 2135

jorgen.winroth@sobi.com

ⁱ L.A. Levine Peyronie's Disease: A Guide to Clinical Management. Humana Press: 10-17, 2007.

ⁱⁱ Ralph D et al. *J Sex Med.* 2010;7(7):2359-2374.