



# **PRESS RELEASE**

Chesterbrook, Pa., USA and Stockholm, Sweden, 25 June, 2014

# Sobi files for EU approval of Xiapex for Peyronies disease

Swedish Orphan Biovitrum AB (publ) (Sobi) and <u>Auxilium Pharmaceuticals, Inc.</u> today announced that Sobi has filed for an extension of the label for Xiapex<sup>®</sup> (collagenase clostridium histolyticum) with the European Medicines Agency (EMA) to include the indication of Peyronie's disease.

The filing is based on positive safety and efficacy outcome data from two double-blind placebo-controlled studies, IMPRESS I and II (The Investigation for Maximal Peyronie's Reduction Efficacy and Safety Studies) which evaluated Xiapex for the treatment of Peyronie's disease. The EMA filing follows the approval from the United States Food and Drug Administration (FDA) in December 2013 of Xiaflex<sup>®</sup> (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. Xiaflex is the tradename for Xiapex used in the United States.

"We believe that Xiapex, if approved for this new indication, has the clinical profile to make a major contribution to the field in Peyronie's disease," says Anders Edvell, MD, PhD, Vice President Sobi Partner Products.

Xiapex is approved in Europe for the treatment of Dupuytren's contracture in adult patients with a palpable cord. Sobi is Marketing Authorisation Holder (MAH) for Xiapex in 28 EU member countries, as well as Norway and Iceland. Sobi holds the exclusive rights to commercialise Xiapex for Dupuytren's contracture and Peyronie's disease indications in these countries subject to applicable regulatory approvals.

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## 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 cases<sup>1</sup>. After approximately 12 months of disease, the disease is reported to often develop into a more chronic, stable phase<sup>1</sup>. The incidence of PD is estimated between 3 and 9 percent<sup>ii</sup>; however the disease is thought to be underdiagnosed and undertreated<sup>1</sup>.

## About Xiapex

Xiapex (collagenase clostridium histolyticum), is a pharmacological treatment for 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 reduces the contraction. It is administered by local injection directly into the



Dupuytren's cord – a procedure which can be carried out in an outpatient setting. 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 finger.

#### 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 Haemophilia 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 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 <u>www.sobi.com</u>.

#### **About Sobi Partner Products**

Sobi Partner Products (SPP) is a business unit within Sobi which 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 which address important unmet needs, spanning from named patient use (NPU) programs, through to reimbursement and full commercialisation, primarily in the Centre of Expertise setting.

#### **About Auxilium**

Auxilium Pharmaceuticals, Inc. is a fully integrated specialty biopharmaceutical company with a focus on developing and commercializing innovative products for specialist audiences. With a broad range of first- and second-line products across multiple indications, Auxilium is an emerging leader in the men's healthcare area and has strategically expanded its product portfolio and pipeline in orthopedics, dermatology and other therapeutic areas. Auxilium now has a broad portfolio of 12 approved products. Among other products in the U.S., Auxilium markets edex<sup>®</sup> (alprostadil for injection), an injectable treatment for erectile dysfunction, Osbon ErecAid<sup>®</sup>, the leading device for aiding erectile dysfunction, STENDRA<sup>®</sup> (avanafil), an oral erectile dysfunction therapy, Testim<sup>®</sup> (testosterone gel) for the topical treatment of hypogonadism, TESTOPEL<sup>®</sup> (testosterone pellets) a long-acting implantable testosterone replacement therapy, XIAFLEX<sup>®</sup> (collagenase clostridium histolyticum or CCH) for the treatment of Peyronie's disease and XIAFLEX for the treatment of Dupuytren's contracture. The Company also has programs in Phase 2 clinical development for the treatment of Frozen Shoulder syndrome and cellulite. To learn more, please visit <u>www.Auxilium.com</u>.

#### AUXILIUM SAFE HARBOR STATEMENT UNDER THE PRIVATE SECURITIES LITIGATION REFORM ACT OF 1995

This news release contains forward-looking statements as defined by the Private Securities Litigation Reform Act of 1995, including statements made with respect to: whether the EMA will approve Xiapex for the treatment of Peyronie's disease and the effectiveness of such treatment, if approved; and other statements regarding matters that are not historical facts, and involve predictions. These statements involve known and unknown risks, uncertainties and other factors that may cause actual results, performance, achievements or prospects to be materially different from any future results, performance, achievements or prospects expressed in or implied by such forward-looking statements. In some cases you can identify forward-looking statements by terminology such as "may", "will", "should", "would", "expect", "intend", "plan", "anticipate", "believe", "estimate", "predict", "potential", "seem", "seek", "future", "continue", or "appear" or the negative of these terms or similar expressions, although not all forward-looking statements contain these identifying words. Although forward-looking statements are based on Auxilium's current plans or assessments that are believed to be reasonable as of the date of this press release, they inherently involve certain risks and uncertainties. These forwardlooking statements are subject to a number of risks and uncertainties, including those discussed under "Risk Factors" in Auxilium's Annual Report on Form 10-K for the year ended December 31, 2013 on file with the United States Securities and Exchange Commission ("SEC"), as updated from time to time by Auxilium's Quarterly Reports on Form 10-Q and, where applicable, Current Reports on Form 8-K, and in other public filings with the SEC. While Auxilium may elect to update the forward-looking statements made in this news release in the future, Auxilium specifically disclaims any obligation to do so. Auxilium's SEC filings may be accessed electronically by means of the SEC's home page on the Internet at http://www.sec.gov. There may be additional risks that Auxilium does not presently know or that Auxilium currently believes are immaterial which could also cause actual results to differ from those contained in the forward-looking statements.



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"SDI and data on file, Auxilium

<sup>&</sup>lt;sup>i</sup> L.A. Levine Peyronie's Disease: A Guide to Clinical Management. Humana Press: 10-17, 2007. <sup>ii</sup> Ralph D et al. *J Sex Med*. 2010;7(7):2359-2374.