

## PRESS RELEASE

Chesterbrook, PA, and Stockholm, Sweden, July 16, 2013



### **AUXILIUM PHARMACEUTICALS, INC. AND SWEDISH ORPHAN BIOVITRUM AB (PUBL) ENTER A COLLABORATION AGREEMENT FOR XIAPEX® IN 71 EURASIAN AND AFRICAN COUNTRIES**

*-Sobi Obtains Exclusive Rights for One Commercial and One Development Indication for XIAPEX-  
-In Addition to Royalties, Auxilium to Receive up to \$40 M in Potential Aggregate Sales Milestones-*

Auxilium Pharmaceuticals, Inc. (NASDAQ: AUXL) and Swedish Orphan Biovitrum AB (publ) (STO: SOBI) announced today that they have entered into a long-term collaboration for the development, supply and commercialization of XIAPEX (collagenase clostridium histolyticum), a novel, first-in-class biologic for the treatment of Dupuytren's contracture. In addition, work is on-going to file for approval of XIAPEX for the treatment of Peyronie's disease in the EU.

Under the terms of the collaboration agreement, Sobi will receive exclusive rights to commercialize XIAPEX for these two indications, subject to applicable regulatory approvals, in 28 EU member countries, Switzerland, Norway, Iceland, 18 Central Eastern Europe/Commonwealth of Independent countries, including Russia and Turkey, and 22 Middle Eastern & North African countries. Since 2011, XIAPEX has been approved for the treatment of Dupuytren's contracture in 28 EU member countries, Switzerland, and Norway. Sobi, via its Partner Products business unit, will be primarily responsible for the applicable regulatory, clinical and commercialization activities for XIAPEX in Dupuytren's contracture and Peyronie's disease in these countries.

XIAFLEX®/XIAPEX has been approved by the U.S. Food and Drug Administration, Health Canada and the European Medicines Agency as a treatment for Dupuytren's contracture for adult patients with a palpable cord, and is also in phase III development in Japan. In addition, a XIAFLEX submission has been filed for approval in Australia for the treatment of Dupuytren's contracture.

"Today, Sobi and Auxilium have established a broad relationship, which we believe will build on the momentum and growth of XIAPEX in the EU territories and to also offer, subject to regulatory approval, the first, effective nonsurgical treatment for two diseases in multiple new geographies," said Adrian Adams, Chief Executive Officer and President of Auxilium. "With the proven strength of Sobi's commercialization and development organization in these diverse markets, this relationship should further enhance our ability to bring this innovative product to a global audience."

"This relationship has been designed to leverage Sobi's extensive regulatory and marketing expertise, as well as our established local operating companies in many of these markets," said Geoffrey McDonough, Chief Executive Officer and President of Sobi. "XIAPEX already has a growing Dupuytren's physician base in the EU territories, and we plan to build on our track-record of achieving sustainable patient access to new and

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innovative treatments to make XIAPEX a sustainable global solution for patient communities with few treatment options today.”

Under the terms of the collaboration agreement, Auxilium will receive significant tiered double-digit royalties based on sales of XIAPEX in Sobi’s territories, which will also cover payment for product supply. Additionally, Sobi could make up to \$40 million in potential sales milestone payments to Auxilium.

Auxilium will remain primarily responsible for the global development of XIAPEX in Dupuytren’s contracture and Peyronie’s disease and will be responsible for drug manufacturing and supply. Sobi will be responsible for clinical development and regulatory activities and associated costs corresponding to any additional trials required in its licensed territories.

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#### **About Dupuytren’s contracture**

Dupuytren’s contracture is a chronic condition that affects the connective tissue that lies beneath the skin in the palm. The disease is progressive in nature. Typically, skin pits then nodules develop in the palm as collagen deposits accumulate. As the disease progresses, the collagen deposits form a cord that stretches from the palm of the hand to the base of the finger. Once this cord develops, the patient’s fingers contract and the function of the hand is impaired. The incidence of Dupuytren’s disease, inclusive of pits, nodules and cords, is highest in Caucasians, historically those of Northern European descent, with a global prevalence of four to six percent of the Caucasian population<sup>1</sup>. Most cases of Dupuytren’s contracture occur in patients older than 50 years<sup>2</sup>.

- (1) The most frequently affected parts of the hand associated with Dupuytren’s contracture are the joints called the Metacarpophalangeal Joint, or MP joint, which is the joint closest to the palm of the hand and the Proximal Interphalangeal Joint, or the PIP joint, which is the middle joint in the finger. The little finger and ring finger are most frequently involved. XIAFLEX is the only drug approved by the U.S. Food and Drug Administration, European Medicines Agency and Health Canada for treatment of Dupuytren’s contracture, which has historically been treated primarily by an open surgical procedure. Hurst, L. C. et al., *Injectable Collagenase Clostridium Histolyticum for Dupuytren’s Contracture*, *New England Journal of Medicine*, (2009; 361:968-979)
- (2) Badalamente, M. A., Hurst, L. C. et al., *The Journal of Hand Surgery*, (2002; 27A:788-798)

#### **About Peyronie’s Disease**

PD can be a physically and psychosocially devastating disorder that results in varying degrees of penile curvature deformity and disease bother associated with painful erections, erection appearance, impact on intercourse, and intercourse frequency. PD is the development of collagen plaque, or scar tissue, on the shaft of the penis that may harden and reduce flexibility, thus occasionally causing pain and causing the penis to deform in a bend or arc during erection. PD is a heterogeneous disease with an initial inflammatory component. This inflammatory phase is poorly understood with a somewhat variable disease course and occasional spontaneous resolutions of not greater than 13%<sup>1</sup>. After 12-18 months of disease, the disease is reported to often develop into a more chronic, stable phase<sup>1</sup>. The estimated prevalence of PD in adult men has been reported to be approximately 5%<sup>2</sup>; however the disease is thought to be underdiagnosed and undertreated<sup>1</sup>. Based on U.S. historical medical claims data, it is estimated that between 65,000 and 120,000 PD patients are diagnosed every year, but only 5,000 to 6,500 PD patients are treated with injectables or surgery annually<sup>3</sup>.

- (1) L.A. Levine *Peyronie’s Disease: A Guide to Clinical Management*. Humana Press: 10-17, 2007.
- (2) Bella A. *Peyronie’s Disease* *J Sex Med* 2007;4:1527–1538
- (3) SDI and data on file, Auxilium



#### **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 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).

#### **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 commercialization, primarily in the Centre of Expertise setting.

#### **About Auxilium**

Auxilium Pharmaceuticals, Inc. is a specialty biopharmaceutical company with a focus on developing and marketing products to predominantly specialist audiences. Auxilium markets Testim® 1% (testosterone gel) for the topical treatment of hypogonadism in the U.S. and XIAFLEX® (collagenase clostridium histolyticum (CCH)) for the treatment of adult Dupuytren's contracture patients with a palpable cord in the U.S. GlaxoSmithKline LLC co-promotes Testim with Auxilium in the U.S., while Ferring International Center S.A. markets Testim in certain countries of the EU and Paladin Labs Inc. markets Testim in Canada. Swedish Orphan Biovitrum AB (publ) has marketing rights for XIAPEX® (the EU tradename for collagenase clostridium histolyticum) in 71 Eurasian and African countries. Asahi Kasei Pharma Corporation has development and commercial rights for XIAFLEX in Japan; and Actelion Pharmaceuticals Ltd has development and commercial rights for XIAFLEX in Canada and Australia. As a result of its recent acquisition of Actient Holdings, LLC, Auxilium now markets TESTOPEL®, the only long-acting implantable testosterone replacement therapy, Edex®, the leading branded non-oral drug for erectile dysfunction, Striant®, a buccal system for testosterone delivery, and Osbon ErecAid®, a device for aiding erectile dysfunction, and also has a non-promoted respiratory franchise, including Theo-24® and Semprex®-D, along with three other non-promoted products. Auxilium has three projects in clinical development. XIAFLEX is in phase III of development for the treatment of Peyronie's disease. CCH is in phase II of development for the treatment of Frozen Shoulder syndrome (adhesive capsulitis) and phase II of development for the treatment of cellulite (edematous fibrosclerotic panniculopathy). Auxilium also has rights to pursue additional indications for XIAFLEX. For additional information, visit <http://www.auxilium.com>.

#### **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, which discuss matters that are not facts, and may include words to indicate their uncertain nature such as "believe," "expect," "anticipate," "intend," "plan," "should," "could," "estimate," "project," "will," and "target." Our forward-looking statements convey management's expectations, beliefs, plans and objectives regarding future performance of the Company and are based upon preliminary information and management assumptions. No specific assurances can be given with respect to whether: we will develop XIAPEX/XIAFLEX for the treatment of multiple potential indications, achieve the results or indicated timing of clinical trials for XIAPEX/XIAFLEX for the additional indications or be successful in commercializing XIAPEX/XIAFLEX for the additional indications; our collaboration with Sobi will improve on the growth of XIAPEX in the EU territories; regulatory approval will be obtained for XIAPEX in any of Sobi's licensed territories within the anticipated timeframes, if at all; our collaboration with Sobi will enable us to bring XIAPEX to a global market; Sobi will be successful in developing and commercializing XIAPEX in its licensed territories; or we will receive the indicated milestone or royalty payments from Sobi. While the Company may elect to update the forward-looking statements made in this news release in the future, the Company specifically disclaims any obligation to do so. Such forward-looking statements are subject to a wide range of risks and uncertainties that could cause results to differ in material respects, including those relating to product development, revenue, expense and earnings expectations, intellectual property rights, results and timing of clinical trials, success of marketing efforts, the need for additional research and testing, and the timing and content of decisions made by regulatory authorities, including the U.S. Food and Drug Administration, and those risks discussed in our reports on file with the Securities and Exchange Commission (the "SEC"). Our SEC filings may be accessed electronically by means of the SEC's home page on the Internet at <http://www.sec.gov> or by means of the Company's home page on the Internet at <http://www.auxilium.com> under the heading "For Investors - SEC Filings." There may be additional risks that the Company does not presently know or that the Company currently believes are immaterial which could also cause actual results to differ from those contained in the forward-looking statements.



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