PRESS RELEASE

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Xiapex® gets recommendation to be made available on National Health Service in England

Swedish Orphan Biovitrum AB (publ) (Sobi™) today announces that for the first time people in England with the disabling hand condition Dupuytren's disease will have access to Xiapex® (collagenase clostridium histolyticum (CCH)) injections, a pharmacological treatment for contracture of their fingers, on the National Health Service (NHS) after recommendation from The National Institute for Health and Care Excellence (NICE).

"The availability of funding for Xiapex within NHS England is an important milestone for the Dupuytren's community in the UK, as healthcare professionals can now offer people with contracture a non-invasive treatment option," says Neil Dugdale, General Manager UK & RoI at Sobi. "We are pleased that Sobi was able to work with NICE and ultimately achieve access for Dupuytren's contracture patients in England. We are very grateful for the support of both the British Dupuytren's Society and the British Society for Surgery of the Hand during this process."

NICE recommends CCH as an option for treating Dupuytren's contracture with a palpable cord in adults who are not taking part in an ongoing clinical trial comparing CCH to limited fasciectomy, if all of the following apply:

- There is evidence of moderate disease (functional problems and metacarpophalangeal joint contracture of 30° to 60°and proximal interphalangeal joint contracture of less than 30° or first web contracture) plus up to 2 affected joints.
- Percutaneous needle fasciotomy (PNF) is not considered appropriate, but limited fasciectomy is considered appropriate by the treating hand surgeon.
- The choice of treatment (CCH or limited fasciectomy) is made on an individual basis after discussion between the responsible hand surgeon and the patient about the risks and benefits of the treatments available.
- 1 injection is given per treatment session by a hand surgeon in an outpatient setting.

Xiapex® was granted a marketing authorisation by the European Commission for the treatment of Dupuytren's contracture in adult patients with a palpable cord in 2011, and was the first pharmacological treatment approved in the EU for treating this condition.[1]

Sobi and the Specialty Pharmaceutical Company Endo have 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 the Marketing Authorisation Holder (MAH) for Xiapex in the 28 EU Member States, as well as Norway and Iceland. Xiaflex® (collagenase clostridium histolyticum) is the trade name for Xiapex used in the United States.

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About Dupuytren's disease

Dupuytren's disease, also known as "Viking disease", is a condition that affects the connective tissue in the palm of the hand and the inside surface of the fingers.[2] It occurs when a collagen nodule forms in the palm of the hand resulting in a small lump. Eventually this can develop into a long "cord" in the palm which then contracts resulting in the finger being drawn in towards the palm of the hand. This is known as Dupuytren's contracture which makes everyday tasks such as driving a car and opening a jar difficult. The name "Viking disease" originates from the belief that the disease first appeared among the Vikings. Dupuytren's disease affects 3-6 percent of the Caucasian population,[3] mostly in men over the age of 50. Although the underlying cause of the disease is not known, the most common cause is hereditary with 70 percent of those affected having the disease in their family.[3] Dupuytren's cannot be cured but can be treated by both surgery and non-invasive methods. To find out more about Dupuytren's disease please visit www.thisisdupuytrens.com

About Xiapex

Xiapex (collagenase clostridium histolyticum) is approved for the treatment of Dupuytren's contracture in adult patients with a palpable cord and for adult men with Peyronie's disease with a palpable plaque and curvature deformity of at least 30 degrees at the start of therapy. 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. 24 – 72 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 affected finger. As a complement to Xiapex injection treatment for Peyronie's disease, modelling of the penis is needed. Modelling is performed 1 – 3 days after the second injection of the cycle in an attempt to further disrupt the plaque and help straighten the penis. More information relating to Xiapex can be found at www.xiapex.eu.

About Sobi™

Sobi is an international specialty healthcare company dedicated to rare diseases. Sobi's mission is to develop and deliver innovative therapies and services to improve the lives of patients. The product portfolio is primarily focused on Haemophilia, Inflammation and Genetic diseases. Sobi also markets a portfolio of specialty and rare disease products across Europe, the Middle East, North Africa and Russia for partner companies. Sobi is a pioneer in biotechnology with world-class capabilities in protein biochemistry and biologics manufacturing. In 2016, Sobi had total revenues of SEK 5.2 billion (USD 608 M) and about 760 employees. The share (STO: SOBI) is listed on Nasdaq Stockholm. More information is available at www.sobi.com.

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[1] Xiapex Summary of Product Characteristics (SmPC).
[2] Townley WA et al. Clinical review: Dupuytren's contracture unfolded. BMJ 2006;332:397–400
[3] Ling RS. The genetic factor in Dupuytren's disease. J Bone Joint Surg Br. 1963;45:709–18.