# Xbrane Biopharma AB: Xbrane submits GMP approval application for the production facility for Spherotide according to time plan

Press Release2016-08-01

Xbrane submits GMP approval application for the production facility for Spherotide according to time plan

Xbranes subsidiary Primm Pharma has, according to the time plan, submitted the application to AIFA, the Italian Medicines Agency, for GMP approval of its production facility for Spherotide situated outside Naples, Italy. AIFA will during the coming 6 months make an evaluation, including a visit of the facility and if no concerns are reported an approval can be expected by early 2017.

Spherotide is a depot formulation with the GnRH analogue triptorelin as active substance. Triptorelin had annual sales of 446 MUSD during 2015 (Source IMS Health) and is used in the treatment of prostate cancer, endometriosis and uterine fibroids. The GMP approval is required for Xbrane to be able to produce Spherotide for human use and is a critical step in the development process.

Xbrane acquired Primm Pharma in September 2015 for 56 MSEK in form of a convertible note that can be converted into shares in Xbrane Biopharma AB (publ) at 42,5 SEK per share based on fulfilment of six milestones related to the development of Spherotide. The submission of the GMP application to AIFA is the first milestone in the above mentioned convertible note and entitles the holders, the previous owners of Primm Phrma, to convert 10% of the note, corresponding to 132 243 shares in Xbrane Biopharma AB (publ). The conversion will happen after formal request from the holders of the note and formal approval by the board of directors of Xbrane. The shares will be new issued shares by Xbrane.

"We are very happy to submit the application for GMP approval to AIFA in line with our time plan. The GMP approval is a critical step for us in the development process towards market approval and initiated sales of Spherotide in Iran and other markets." says Martin Ã…mark, CEO of Xbrane Biopharma AB.

About Xbrane Xbrane is a commercial phase Swedish biopharmaceutical company specialized in High Demand Complex Generics. Xbrane has world leading expertise in developing generics for injectable controlled release drugs and proprietary high yield protein expression technology for the development of biosimilars. The goal is to become a global leader within the company's portfolio of High Demand Complex Generics. Xbranes headquarter is located in Stockholm and the company's in-house research and development facilities are in Sweden and Italy. Xbrane is listed at Nasdaq First North since February 3rd under the name XBRANE and Avanza Bank AB is Xbranes certified advisor. For more information see www.xbrane.com.

For further information, please contact:Martin AmarkChief Executive OfficerM: +46 (0) 763-093 777E: martin.amark@xbrane.com





*https://www.bioportfolio.com/news/article/2794844/Xbrane-Biopharma-AB-Xbrane-submits-GMP-approval-application-for-the-production-facility.html*