Press release
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Positive outcome of inspection from Italian Medicines Agency - GMP approval of Xbrane's Spherotide production facility is expected in Q1 2017

The positive outcome of the inspection of the production facility confirms Xbranes expectation of receiving GMP approval and to be able to ship its first commercial batch of Spherotide at a value of SEK 7 million in Q1 2017.

In August 2016 Xbrane´s fully owned subsidiary submitted the application for GMP approval of the production facility for Spherotide to AIFA, the Italian Medicines Agency. AIFA has now completed the inspection of the production facility with positive outcome. Only minor deviations were identified which will be adjusted and reported back to AIFA within 30 days. Hence, GMP approval is expected in Q1 2017. The facility currently has capacity to produce approximately 50% of global annual volume of the originator drug that Spherotide addresses and can be expanded if need be. Upon approval Xbrane will ship its first commercial batch of Spherotide to its distribution partner in the Middle East. Distribution deals for other regions are expected during Q1-Q2 2017.

"We are very pleased with the outcome of the AIFA inspection. We are confident that we will receive the GMP approval in Q1 2017 allowing us to keep our focus on signing new licensing and distribution partnerships across the world, "says Martin Åmark, CEO of Xbrane Biopharma.

Spherotide is a generic to the drug Decapeptyl® with global sales of approximately SEK 4 billion. It is a formulation with long acting effect after injection with the active substance triptorelin and is used primarily in the treatment of prostate cancer, endometriosis and uterine fibroids. The drug is based on encapsulation of the active substance in biodegradable microspheres that degrade in the body after injection and create a long acting effect. Spherotide is the only generic to Decapeptyl®.

About Xbrane
Xbrane is a commercial phase Swedish biopharmaceutical company specialized in High Demand Biosimilars and long acting injectables. Xbrane has world leading expertise in developing generics for long acting injectable drugs and proprietary high-yield protein expression technology for the development of biosimilars. Xbranes's 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 Xbrane´s certified advisor. For more information see www.xbrane.com.

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