

## Press release

2016-10-31

### **Xbrane Biopharma AB (“Xbrane”) has received scientific advice regarding regulatory and clinical aspects of the planned submission of a Marketing Authorization Application (MAA) for Spherotide in EU**

Xbrane has received scientific advice from BfArM, the German Federal Institute for Drugs and Medical Devices, with regards to the clinical and regulatory aspects of the Company’s planned submission of a Marketing Authorization Application (MAA) for Spherotide 1-month formulation for EU. A Market Authorization in EU would enable Xbrane to sell and market Spherotide in Europe and would serve as a base and facilitator for the approval process in other regions.

The MAA will, according to the advice received by BfArM, be supported by a single pivotal clinical trial in prostate cancer patients. The clinical efficacy of Spherotide will be measured as testosterone suppression under castration level one month after initiated treatment. The secondary endpoints suggested by Xbrane were all accepted by BfArM. Xbrane estimates that the clinical trial will involve 150-170 prostate cancer patients and will be initiated first half of 2017. In accordance with Xbrane’s commercialization strategy for Spherotide the study shall be co-funded by the future European sales and marketing partner.

“We are happy to gain support for our regulatory and clinical strategy in discussions with BfArM. The advice was pragmatic and concrete and we are very confident that the discussed thresholds for efficacy are achievable. This allows us to proceed with all activities required for finalizing the MAA for EU, ” Martin Åmark, CEO Xbrane Biopharma

Xbrane plans to file a MAA under directive 2001/83/EC article 10(3) following the decentralized procedure with Germany as the Reference Member State (RMS), and including other main European countries.

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 Biopharma AB**

*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 3<sup>rd</sup> under the name XBRANE and Avanza Bank AB is Xbrane’s certified advisor. For more information see [www.xbrane.com](http://www.xbrane.com).*

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