

**Press release**  
**2018-12-19**

## **Xbrane Biopharma has submitted the first application for start of Xlucane clinical trial**

**Xbrane Biopharma has submitted its first national Clinical Trial Application (CTA) to the Food and Drug Administration (FDA) in the United States for the start of the Xplore trial for Xlucane, Xbrane Biopharma's lead candidate. This application represents a significant milestone as the product enters the pivotal phase III trial that will support the Marketing Authorization Application.**

*"It is with great satisfaction we can announce that our first clinical trial application has been submitted to the first national regulatory authority. Submission of the applications in the remaining countries will be done over the course of the coming 1-2 months. The start of the trial is planned for March 2019 when we also expect to recruit our first patient. After having demonstrated high similarity in-vitro and in-vivo to the originator, it is with great excitement and confidence that we enter into this pivotal phase III trial with Xlucane", says CEO Martin Åmark.*

### **About the Xplore trial**

The Xplore trial is a phase III trial designed to confirm biosimilarity with regards to safety, efficacy and immunogenicity of Xlucane versus Lucentis® in patients with wet form of age-related macular degeneration (wAMD). The study design was developed in consultation with the Food and Drug Administration (FDA) in the United States and the European Medicines Agency (EMA). The primary efficacy end-point of the trial is change in visual acuity after eight weeks of treatment, for which the confidence interval of the difference between Xlucane and Lucentis® needs to fall within a pre-defined equivalence margin. In addition, several secondary endpoints related to efficacy, safety and immunogenicity are followed over the full treatment period of 12 months. The study will involve approx. 600 patients across approx. 150 sites in 16 countries and is expected to support the registration of Xlucane across majority of regions globally. Xbrane has for the Xplore trial contracted the global CRO Syneos Health which has conducted some of the largest trials in recent years in the wAMD patient population. Xbrane will communicate in relation to the progress of the trial at following milestones: first regulatory approval, first patient in, last patient in, top-line data on the primary endpoint and final study report.

### **About Xlucane**

Xlucane is a ranibizumab (Lucentis®) biosimilar candidate developed by Xbrane Biopharma. Xlucane has demonstrated high analytical similarity compared to Lucentis® in a panel of methods in accordance with requirements from EMA and FDA as well as equivalent pharmacokinetic profile and tolerability in-vivo compared to Lucentis®. Xbrane has entered a co-development agreement with STADA Arzneimittel AG regarding Xlucane under which the companies finance the continued development of the product 50/50 and will share the profits from sales and marketing of the product 50/50.

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**About Xbrane**

*Xbrane is a commercial phase Swedish biopharmaceutical company specialized in biosimilars. Xbrane has a patented protein production platform for development of biosimilars and world leading expertise in biosimilars. Xbrane's headquarter is located in Solna outside of 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, 2016 under the name XBRANE and Avanza Bank AB is Xbrane's certified adviser. For more information see [www.xbrane.com](http://www.xbrane.com).*

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