Press release
2019-01-18

Xbrane Biopharma announces acceptance of initiation of Xlucane clinical trial in the US

The Food and Drug Administration (FDA) and the Central Ethics Committee in the United States have accepted Xbrane´s IND application for initiation of the Xplore trial, a phase III trial with Xlucane, a ranibizumab (Lucentis®) biosimilar candidate.

"It is with great satisfaction we can announce acceptance from the FDA and the Central Ethics Committee to initiate the Xplore trial. Applications to the additional countries are being submitted continuously during January and February. First patient in is expected for March 2019.", 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 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.

For further information, please contact:

Martin Åmark
Chief Executive Officer
M: +46(0) 763-093 777
E: martin.amark@xbrane.com

Susanna Helgesen
CFO/IR, Xbrane Biopharma AB
M: +46 (0) 708-278 636
E: susanna.helgesen@xbrane.com

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 (corp@avanza.se, +46 (0)8 409 421 20) is Xbrane's certified adviser. For more information see www.xbrane.com.

This information is information that Xbrane Biopharma AB (publ) is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the contact person set out above, at 18 January 8:00.