First patient dosed in the phase III-study Xplore.

Solna, Sverige. 19 April 2019 – Xbrane Biopharma AB (Nasdaq Stockholm First North: XBRANE) announces today that the first patient has been dosed in the Xplore study.

"We are pleased to announce that the first patient has been included and dosed in our Xplore trial and that the trial is proceeding according to plan and recruitment of patients is expected to be completed during this year." said CEO Martin Åmark.

About the Xplore trial

The Xplore trial is 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, serval secondary endpoints related to efficacy, safety and immunogenicity are followed over the full treatment period of 12 months. The study will involve approximately 600 patients across approximately 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 with long experience from conducting clinical trials in the targeted patient population. Xbrane will communicate in relation to the progress of the trial at following milestones: 50% of patients recruited, last patient recruited, full data read out on primary end-point and final study report including full data read out on secondary end-points.

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 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 Us

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 (corp@avanza.se, +46 (0)8 409 421 20).
For more information see www.xbrane.com.

This information is information that Xbrane Biopharma is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the contact persons set out above, at 2019-04-19 19:00 CEST.

Attachments

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