Xbrane announces positive top-line results from the pivotal phase III equivalence trial for Xlucane™ - a biosimilar candidate to Lucentis®

Xbrane Biopharma AB (publ) ("Xbrane" or "the Company") (Nasdaq Stockholm: XBRANE) today announced top-line results from the 12-months data from the Phase III equivalence trial Xplore with the Lucentis® biosimilar candidate Xlucane™, these data support the ongoing registration process for Xlucane™. As previously announced, Xlucane™ met the primary endpoint demonstrating equivalent efficacy in the change of BCVA (Best Corrected Visual Acuity) at week 8 of treatment compared to Lucentis®. Further, the full 12-months data, as per Xbrane´s assessment, reveals no clinically meaningful differences between Xlucane™ and Lucentis®.

"These results from the pivotal Xlucane™ phase III study represents a significant milestone for Xbrane to become a leading global biosimilar developer," said Xbrane's Chairman of the Board, Anders Tullgren.

As communicated on June 27, 2021, based on an interim-read out, Xlucane™ met the primary endpoint in Xplore demonstrating equivalent efficacy measured in improvement in BCVA at week 8 compared to Lucentis®. Equivalence was determined since the two-sided 95% confidence interval around the difference in change in BCVA at week 8 between Xlucane™ and Lucentis® was within the pre-defined equivalence margin as agreed with the EMA and FDA.

The last patient had their last visit in November 2021 and the full 12-months data from all patients in the study has now been compiled and analyzed. As per Xbrane´s assessment, the Xplore study reveals no clinically meaningful differences regarding efficacy, safety, pharmacokinetics, and immunogenicity between Xlucane™ and Lucentis®.

"*I would really like to thank all of the clinics and patients who took part in Xplore for making this possible despite the ongoing COVID-19 pandemic,"* said Xbrane's CEO Martin Åmark

About Xlucane™

Xlucane™ is a biosimilar candidate to Lucentis®, a VEGF-a inhibitor used in the treatment of serious eye diseases, mainly wet age-related macular degeneration (wAMD) and diabetic macular edema (DME). The market for oftalmic VEGFa inhibitors generates net-sales of about €10 billion annually.

About Xplore

Xplore is a randomized, double-blinded, multi-center study evaluating efficacy, safety, pharmacokinetics, and immunogenicity of Xlucane™ compared to Lucentis® in patients with wAMD. The primary endpoint in the study is the change in BCVA at week 8. wAMD patients were randomized (1:1) to receive monthly injections of Xlucane™ or the reference product, Lucentis®, for a duration of one year. Around 140 clinics in 15 countries contributed to the successful recruitment of the 583 patients in November 2020, despite the challenges due to the COVID-19 pandemic.

Contacts

Martin Åmark, CEO
M: +46 76 309 37 77
E: martin.amark@xbrane.com

Anette Lindqvist, CFO/IR
M: +46 76 325 60 90
E: anette.lindqvist@xbrane.com

About Us

Xbrane Biopharma AB develops biological drugs based on a patented platform technology that provides significantly lower production costs compared to competing systems. Xbrane has a portfolio of biosimilar candidates targeting €28 billion in annual sales of the respective reference products, with the leading one under registration in Europe. Xbrane's head office is in Solna, just outside Stockholm. Xbrane is listed on Nasdaq Stockholm under the ticker XBRANE. For more information, visit 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 2022-02-15 08:00 CET.

Attachments

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