

Xlucane™ meets the primary endpoint in the pivotal Phase III trial with Xlucane™ – regulatory submission in EU and US planned for second half of 2021

Xbrane Biopharma AB (publ) ("Xbrane" or "the Company") (Nasdaq Stockholm: XBRANE) today announces top-line results from the 6 months interim read-out in the pivotal Phase III equivalence trial with the Lucentis® biosimilar candidate Xlucane™. Xlucane™ met the primary endpoint demonstrating equivalent efficacy in change of BCVA (Best Corrected Visual Acuity) at week 8 of treatment compared to Lucentis®. Xbrane confirms the plans to submit the Marketing Authorization Application (MAA) to European Medicines Agency (EMA) in Q3 2021 and the Biologics License Application (BLA) to US Food and Drug Administration (FDA) in Q4 2021 on the basis of the interim results. Xbrane and its co-development partner STADA Arzneimittel AG ("STADA") are committed to bring Xlucane™ to market and contribute to an increased worldwide access to an effective and safe treatment option to millions of patients suffering from serious eye diseases.

Xlucane™ is a biosimilar candidate to Lucentis®, a VEGF-a inhibitor used in treatment of serious eye diseases, mainly wet age-related macular degeneration (wAMD) and diabetic macular edema (DME). 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 (Best Corrected Visual Acuity) 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. Approximately 140 clinics in 15 countries contributed to a successful recruitment completion of the 583 patients in November 2020, this despite the challenges due to the COVID-19 pandemic. An interim read-out was performed when the last patient had reached month 6 in the treatment schedule.

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 EMA and FDA. Furthermore, no clinically meaningful differences on secondary endpoints regarding pharmacokinetic, safety and immunogenicity between Xlucane™ and Lucentis® could be observed. Xbrane will receive data on additional secondary endpoints and analyze these further, along with above mentioned endpoints, during this summer. The complete dataset is planned to be presented in a scientific journal or at a scientific conference during 2022 at the earliest.

Xbrane confirms the plans to proceed towards submission of the MAA and BLA in Q3 2021 and Q4 2021, respectively. As per agreement with both authorities the application will be complemented with the final study report during Q1 2022 including full 12 months treatment data from all patients. The authorities will assess the application on a totality of evidence principle for which the full 12 months clinical data from Xplore as well as the analytical comparability package will be crucial components.

"The positive interim results from the large Xlucane™ phase III study represents yet another significant milestone for Xbrane Biopharma to become a leading global biosimilar developer", comments Xbrane Chairman of the Board Anders Tullgren.

"I want to extend a big thank you to all clinics and patients having participated in Xplore for making this possible despite the ongoing COVID-19 pandemic. We are now on track towards filing of Xlucane™ in Europe and the US during second half of 2021", says Xbrane CEO Martin Åmark

Xplore Webcast

Xbrane will host a webcast for investors, analysts and journalists, in which the company will discuss the interim results and provide an update on the Xlucane™ development program. The webcast is sent tomorrow Monday June 28th, 2021, 14.00-14.45 CET. Please register using the following link:

Weblink

<https://tv.streamfabriken.com/press-conference-20210628>

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About Us

Xbrane Biopharma AB develops biological drugs based on a platform technology that provides significantly lower production costs compared to competing systems. Xbrane's leading product Xlucane™, a Lucentis® biosimilar candidate, addresses the SEK 106 billions ophthalmic VEGFa inhibitor market. Xlucane™ is in phase III and filing of marketing authorization application is planned for the latter part of 2021. Xbrane has additionally three biosimilars in its pipeline targeting SEK 100 billions in originator sales. 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 2021-06-27 22:40 CEST.

Attachments

[Xlucane™ meets the primary endpoint in the pivotal Phase III trial with Xlucane™ – regulatory submission in EU and US planned for second half of 2021](#)