Xbrane announce U.S. FDA filing acceptance for a Lucentis® (ranibizumab) biosimilar candidate

Xbrane Biopharma AB (publ) ("Xbrane" or "the Company") (Nasdaq Stockholm: XBRANE) today announced the acceptance of the supplemental Biologics License Application (sBLA) for a Lucentis® (ranibizumab) biosimilar candidate by the US Food and Drug Administration (FDA). The regulatory process can therefore be initiated with a Biosimilar User Fee Amendment (BsUFA) goal date of April 21st, 2024.

The biosimilar candidate is a VEGF-a inhibitor, intended for the treatment of serious eye diseases such as wet age-related macular degeneration (wAMD), macular edema following retinal vein occlusion and myopic choroidal neovascularization*. In 2018 Xbrane signed a co-development agreement with STADA Arzneimittel AG ("STADA") and in May 2020, the companies signed an exclusive licensing agreement with Bausch + Lomb to commercialize the biosimilar candidate in the United States and Canada.

"Today's sBLA acceptance marks an important step forward for increasing access to VEGF-a inhibitor therapy for all those who benefit from alternative treatment options," said Martin Åmark, CEO, Xbrane. *"Together with STADA and Bausch + Lomb, we will work closely with the FDA during the review process and, if approved, making this new biosimilar available to eye care professionals and their patients throughout the United States."*

The FDA filing is supported by a comprehensive Comparative Analytical Assessment of the biosimilar candidate vs. Lucentis (ranibizumab) and positive data from a randomized, double-masked, multi-center study evaluating efficacy, safety, pharmacokinetics, and immunogenicity of the ranibizumab biosimilar in patients with wAMD. The biosimilar candidate met the primary endpoint in the study by demonstrating equivalent efficacy measured in improvement in best corrected visual acuity (BCVA) at week eight compared to Lucentis®. Equivalence was determined because the two-sided 95% confidence interval around the difference in change in BCVA at week eight was within the pre-defined equivalence margin as agreed with the European Medicines Agency and FDA. Furthermore, no clinically meaningful differences on secondary endpoints regarding pharmacokinetic, safety and immunogenicity versus Lucentis® were observed*.

References

*) Xbrane Biopharma Ab and Stada Arzneimittel AG. Comparing the Efficacy and Safety of Biosimilar Candidate Xlucane® Versus Lucentis® in Patients With wAMD (XPLORE). In: ClinicalTrials.gov [Internet]. 2021- [cited Jan. 24, 2022]. Available from: http://clinicaltrials.gov/show/NCT03805100

LUCENTIS® is a registered trademark of Genentech Inc.

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 EUR 53 billion in estimated annual peak sales of the respective reference product. The lead candidate Ximluci® is granted market authorization approval in Europe and was launched during the first quarter 2023. 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 2023-06-21 09:30 CEST.

Attachments

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