Xbrane Biopharma AB (publ) ("Xbrane" or "the Company") (Nasdaq Stockholm: XBRANE) updates on US FDA BLA (Biologics License Application) for its investigational biosimilar candidate to LUCENTIS® (ranibizumab)

Xbrane re-submitted the BLA (Biologics License Application) for its investigational biosimilar candidate to LUCENTIS® (ranibizumab) to the FDA (US Food and Drug Administration) in December 2024. After submission of additional documentation from the manufacturing sites, the official review cycle was initiated. FDA has now communicated October 21st 2025 as the BsUFA date (decision date). An approval would be subject to successful re-inspections of manufacturing sites. Both Manufacturing sites have addressed observations from FDA inspections during 2024 and submitted the relevant documentation to FDA.

Xbrane is fully committed to advance its investigational biosimilar candidate towards approval in the United States as quickly as possible to provide a much needed, cost-efficient treatment alternative for patients suffering from age-related macular degeneration (AMD), retinal vein occlusion (RVO) or myopic choroidal neovascularization (mCNV).

LUCENTIS® is a registered trademark of Genentech Inc.

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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 26 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 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 2025-05-23 15:05 CEST.

Attachments

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