XBRANE UPDATES ON TIMING FOR RESUBMISSION OF THE BLA FOR ITS RANIBIZUMAB BIOSIMILAR CANDIDATE TO FDA

Xbrane Biopharma AB (publ) ("Xbrane" or "the Company") (Nasdaq Stockholm: XBRANE) plans to re-submit the BLA (Biologics License Application) for its investigational biosimilar candidate to LUCENTIS® (ranibizumab) to FDA (US Food and Drug Administration) in March 2026.

Xbrane received a Complete Response Letter (CRL) to the BLA for its investigational biosimilar candidate to LUCENTIS® (ranibizumab) from the FDA in October 2025. In the CRL FDA mentioned unresolved issues at one of Xbranes contract manufacturers production site involved in the manufacturing of the biosimilar candidate. Subsequently, the site received additional information from the FDA requesting corrective actions related to two specific observations concerning another product that was also included in the scope of the FDA inspection. These corrective actions must be completed before the FDA can approve Xbranes BLA. The work related to these corrective actions is ongoing and will be completed in connection with a planned winter shutdown and related production line re-qualification. Hence, Xbrane will be able to re-submit its BLA post completion of these corrective actions, in March 2026. Xbrane expects a 6 months review process by the FDA of the re-submitted BLA and hence expects a BsUFA date in September 2026.

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 23 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 2025-11-19 08:00 CET.

Attachments

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