XBRANE submits BLA for ranibizumab biosimilar candidate to FDA

Xbrane Biopharma AB (publ) ("Xbrane" or "the Company") (Nasdaq Stockholm: XBRANE) has submitted the BLA (Biologics License Application) for its investigational biosimilar candidate to LUCENTIS® (ranibizumab) to FDA (US Food and Drug Administration)

Xbrane has submitted the BLA for its investigational biosimilar candidate to LUCENTIS® (ranibizumab) to the FDA. Within 60 days, FDA is expected to validate and decide to initiate the review of the BLA. Thereafter, Xbrane expects a 10 month review process and hence an approval could take place during the first half of 2024.

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 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 2023-04-24 07:00 CEST.

Attachments

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