XBRANE PROVIDES AN UPDATE ON RANIBIZUMAB BIOSIMILAR CANDIDATE FDA FILING

Xbrane Biopharma AB (publ) ("Xbrane" or "the Company") (Nasdaq Stockholm: XBRANE) updates the timing for re-submission of the BLA (Biologics License Application) for its investigational biosimilar candidate to LUCENTIS® to first quarter of 2023.

Xbrane withdrew the BLA (Biologics License Application) at the end of May for its investigational biosimilar candidate to LUCENTIS® after receiving feedback from the FDA (U.S. Food and Drug Administration), following a preliminary review, that additional information was required for the FDA to take the decision to accept the BLA and initiate a full review. Xbrane received comments and recommendations from the FDA in June and has since worked intensively together with suppliers, contract manufacturers and partners to address. The delivery of a critical report required for the re-submission has been delayed and therefore the re-submission of the BLA has been postponed to first quarter of 2023.

Xbrane will next update on the BLA upon successful validation by the FDA, which is expected 60 days post re-submission.

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 severe eye diseases.

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® has recently been granted market authorization approval in Europe will be 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 2022-12-15 08:00 CET.

Attachments

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