Xbrane provides update on ranibizumab biosimilar candidate FDA filing

Xbrane Biopharma AB (publ) ("Xbrane" or "the Company") (Nasdaq Stockholm: XBRANE) has received the General Advice letter with comments and recommendations for the resubmission of the BLA (Biologics License Application) for its investigational biosimilar candidate to LUCENTIS® following the preliminary review performed by the FDA (U.S. Food and Drug Administration). Based on the advice received Xbrane plans to resubmit the BLA during 2022.

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 has now received a General Advice letter with comments and recommendations for the resubmission. The majority of the comments and recommendations relate to data or information that is accessible at Xbrane, its contract manufacturers or suppliers. Based on the time required to complete the BLA as per FDAs comments and recommendations, Xbrane plans to resubmit the BLA during 2022.

Provided that all comments and recommendations from the preliminary review are satisfactorily addressed in the application, the BLA will be filed and a full review initiated latest 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 SEK 332 billion in annual sales of the respective reference products, with the leading one under registration in Europe. 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 2022-07-04 08:00 CEST.

Attachments

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