Xbrane provides update on ranibizumab biosimilar candidate FDA filing

Xbrane Biopharma AB (publ) ("Xbrane" or "the Company") (Nasdaq Stockholm: XBRANE) has withdrawn the BLA (Biologics License Application) for its investigational biosimilar candidate to LUCENTIS® after receiving feedback from the FDA (U.S. Food and Drug Administration) that complementary information is required for the FDA to take the decision to accept the BLA and initiate the review.

Xbrane will receive more information about the requested complementary information from the FDA in a few weeks, after which a firm timeline for re-submission of the BLA will be communicated.

Provided that all requested information is satisfactory added, the BLA would be accepted for initiation of review latest 60 days post re-submission.

Xbrane remains 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 2022-05-30 08:00 CEST.

Attachments

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