

Xbrane provides an update on the timeline for resubmission of the market authorization application in the United States

Xbrane Biopharma AB (publ) announces today that the company intends to resubmit its Biologics License Application (BLA) for the ranibizumab biosimilar to the U.S. Food and Drug Administration (FDA) during April/May 2026.

The decision follows after Xbrane's contract manufacturer received further detailed feedback from the FDA related to the Complete Response Letter (CRL) issued in October 2025. The CRL concerned remaining observations at one of the manufacturing sites. No other parts of the BLA application were addressed by the FDA.

According to the FDA's feedback, the contract manufacturer is required to complete all observations before a resubmission can take place, which results in a minor delay to the original plan. The outstanding actions are related to observations concerning the second product that was inspected at the contract manufacturer at the same time as Ximluci. The outstanding corrective actions are expected to be completed and verified at the relevant facility by the end of April 2026, after which Xbrane will resubmit the BLA, with an expected review time of approximately six months.

Xbrane's ranibizumab biosimilar has been approved by EMA and MHRA since November 2022 and has been used commercially in the relevant regions since March 2023.

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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 2026-03-31 18:00 CEST.

Attachments

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