Xbrane Biopharma AB (publ) (“Xbrane” or “the Company”) (Nasdaq Stockholm: XBRANE) receives FDA BsUFA date of October 29, 2026 for its investigational biosimilar candidate to LUCENTIS® (ranibizumab)

Xbrane Biopharma AB (publ) today announced that the U.S. Food and Drug Administration (FDA) has accepted the resubmitted Biologics License Application (BLA) for the Company's investigational biosimilar candidate to LUCENTIS® (ranibizumab) and set a BsUFA (Biosimilar User Fee Act) action date of October 29, 2026.

The BsUFA date marks the target date by which the FDA expects to complete its review of the resubmitted application. The acceptance follows Xbrane's resubmission of the BLA to the FDA in April 2026, which addressed the items raised in the Complete Response Letter received in October 2025.

The candidate is intended to be marketed in the United States under the brand name Lucamzi™.

The product is already approved and marketed in Europe under the brand name Ximluci®, where it was launched in 2023 as a biosimilar to LUCENTIS® (ranibizumab), used in the treatment of a range of retinal disorders.

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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 2026-06-03 18:00 CEST.

Attachments

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