XBRANE SUBMITS RANIBIZUMAB BIOSIMILAR CANDIDATE TO FDA

Xbrane Biopharma AB (Nasdaq Stockholm: XBRANE) has submitted an application for approval (BLA) to the U.S. Food and Drug Administration for its biosimilar candidate to LUCENTIS (ranibizumab).

The original application was submitted in April 2023. In October 2025, the company received a so-called Complete Response Letter (CRL) regarding remaining observations at one of the production facilities. The Authority then required the contract manufacturer to complete all outstanding observations at the production site. The outstanding corrective actions were finalised and verified at the site concerned. Xbrane has therefore resubmitted the BLA. A new review process after resubmission is expected to take around six months.

The company continues to drive the candidate towards approval in the US, with the goal of offering a more cost-effective treatment option for patients with age-related macular degeneration, retinal vein occlusion and myopic choroidal neovascularization, among others.

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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 2026-04-30 08:00 CEST.

Attachments

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