# STADA and Xbrane weigh options for ranibizumab biosimilar candidate

**STADA and Xbrane consider options, including out-licensing for ranibizumab biosimilar candidate in North America. Previous commercial license agreement with Bausch + Lomb discontinued by mutual consent. STADA and Xbrane remain fully committed to securing regulatory approval and bringing ranibizumab to market in U.S. following launch in Europe.**

**Bad Vilbel; Solna – 24th, July 2023 – STADA Arzneimittel AG and Xbrane Biopharma AB (Nasdaq Stockholm: XBRANE)** are considering options, including out-licensing, for their co-developed ranibizumab biosimilar candidate in North America.

The two companies have agreed with their previous commercialization partner, Bausch + Lomb, to discontinue a license agreement for North America that was signed in May 2020. Bausch + Lomb will now focus on other strategic priorities. The upfront payment made by Bausch +Lomb upon entering into the agreement is non-refundable, but no further milestone payments will be made.

Having already launched their cost-effective ranibizumab biosimilar in several European markets* following EU approval in November 2022 under the Ximluci® brand name**, STADA and Xbrane remain fully committed to making this medicine available to patients and ophthalmologists in the U.S. The partners are currently exploring all options, including licensing to an external commercial partner, as well as commercializing the product themselves.

“Our focus is on working with the U.S. regulatory authorities to obtain marketing authorization for ranibizumab and enabling patient access,” explained STADA’s Head of Global Specialty, Bryan Kim. “At the same time, we are accelerating the launch of our Ximluci® ranibizumab biosimilar in Europe.”

In the U.S., the partners’ ranibizumab biosimilar candidate**,** which references the Lucentis® brand**,** was filed with the Food and Drug Administration (FDA) in June 2023, with a Biosimilar User Fee Amendments (BsUFA) action date of 21 April 2024.

“Given that biosimilar competition is just forming in the approximately US$8 billion anti-VEGF market for retinal disorders in North America, we see significant opportunities to improve patient access,” stated Xbrane’s CEO, Martin Åmark. “We are conent that our ranibizumab biosimilar candidate leveraging Xbrane’s patented platform technology has high production yields that can minimize manufacturing costs and ensure a cost-competitive, high-quality therapeutic option.”

In Europe, where the ranibizumab biosimilar in November 2022 received a marketing authorization valid throughout the European Union under the Ximluci® brand name, STADA and Xbrane continue to facilitate patient access. The product has already been launched in several European countries, with more to be added over the coming months.

*) STADA & Xbrane launch ranibizumab to support patient access | STADA
**) STADA and Xbrane secure EU approval for Ximluci® | STADA

**About STADA Arzneimitttel AG**
STADA Arzneimittel is headquartered in Bad Vilbel, Germany. The company focuses on a three-pillar strategy consisting of generics, specialty pharma and consumer healthcare products. Worldwide, STADA sells its products in approximately 120 countries. In financial year 2022, STADA achieved group sales of EUR 3797.2 million and reported earnings before interest, taxes, depreciation and amortization (EBITDA) of EUR884.7 million. As of 31 December 2022, STADA employed 13,183 people worldwide.

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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 53 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 the first quarter 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 2023-07-25 08:00 CEST.*

## Attachments

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