Xbrane and Yongtao enter into exclusive agreement for Ximluci® in Greater China

Xbrane Biopharma AB (publ) ("Xbrane") and Hong Kong Yongtao Pharmaceutical Co., Limited ("Yongtao") today jointly announced that they have entered into an exclusive license and commercialization agreement for Ximluci®, Xbrane's ranibizumab biosimilar, in Mainland China, Hong Kong, Macau and Taiwan.

The agreement brings together Xbrane's biosimilar development, regulatory and manufacturing capabilities with Yongtao's local regulatory, market access and commercial expertise. Yongtao will lead and fund the regulatory registration and commercialization activities in Greater China, while Xbrane will provide the global regulatory, technical and CMC package and retain responsibility for global CMC and manufacturing activities. The parties intend to establish finished-product supply through Xbrane's existing manufacturing network.

The collaboration is intended to create an efficient pathway for Ximluci® to reach patients in Greater China and establishes a shared economic framework for the long-term development and commercialization of the product in the region. The next step for the parties is to seek regulatory advice from NMPA (China National Medical Products Administration) regarding acceptability of the development package of the biosimilar candidate as approved by EMA and US FDA, and specifically any potential need of additional clinical development in local patients. The parties expect to have such feedback in first quarter 2027. If no further development is required, the parties expect to submit the dossier to NMPA in second quarter 2027 with an expected one year regulatory review process.

Financial terms

If the Chinese regulatory authorities confirm that no local pre-approval clinical study is required, Yongtao will, without delay, pay Xbrane an upfront license fee of $2 million. If a local pre-approval clinical study is required, no upfront fee will be payable and Yongtao will lead and fund such study. The parties will share the resulting profit contribution from sales of the product in the territories.

Regulatory and commercial responsibilities

- Yongtao will lead regulatory strategy, registration, market access, pricing, reimbursement and commercialization in Greater China.
- Xbrane will provide the existing global regulatory and technical documentation and regulatory, CMC and technical support required for local filings.
- Yongtao will fund any Mainland China clinical study specifically required by the Chinese regulatory authorities.
- The parties will establish joint governance covering regulatory strategy, clinical development, supply coordination, commercialization planning and financial performance.

Comments from the parties

"This agreement represents an important step in expanding the geographic reach of Ximluci®. Yongtao brings the local regulatory and commercial capabilities required to navigate the Greater China market, while Xbrane contributes the global development, regulatory and manufacturing platform behind the product. Together, we have established a capital-efficient structure with aligned long-term incentives," said Martin Åmark, CEO of Xbrane Biopharma AB.

"We are pleased to partner with Xbrane to bring Ximluci® to Greater China. Retinal vascular diseases represent a significant and growing treatment need across the region. By combining Xbrane's established biosimilar platform and global product package with Yongtao's local regulatory, market access and commercialization capabilities, we aim to build a strong foundation for registration and future launch," said Mr. Hao Xiaofeng, Chairman of Hong Kong Yongtao Pharmaceutical Co., Limited.

Contacts

Martin Åmark, CEO
E: martin.amark@xbrane.com

Jane Benyamin, CFO/IR
E: jane.benyamin@xbrane.com

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 Hagastaden, 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 2026-11-25 16:30 CET.

Attachments

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