Xbrane Provides update on timing of re-submission of BLA for ranibizumab biosimilar candidate

Stockholm/Bad Vilbel/New York – In April 2024 Xbrane Biopharma AB ("Xbrane") received a Complete Response Letter (CRL) from the U.S. Food and Drug Administration (FDA) regarding its Biologics License Application (BLA) for its ranibizumab biosimilar candidate (development name Xlucane™) for treatment of retinal disorders.

FDA requested additional information primarily related to the reference standard and follow-up actions from the pre-approval inspections of manufacturing partners' sites.

Xbrane has since communicated with FDA, and is working together with its partners, including US license holder Valorum Biologics, on addressing the respective requests. Xbrane has the ambition to re-submit the BLA in the fourth quarter of 2024. Should this submission be successful, this would result in a BsUFA date during the second quarter of 2025 assuming a standard 6 month review process and ongoing alignment with the FDA, as well as successful execution of remediation plans of the manufacturing partners.

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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 26 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 2024-07-08 13:00 CEST.

Attachments

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