Xbrane provides regulatory update on FDA review of its ranibizumab biosimilar candidate

Xbrane Biopharma AB ("Xbrane"), a leading Swedish biosimilar developer, announce that the U. S. Food and Drug Administration (FDA) has issued a Complete Response Letter (CRL) to the Company's Biologics License Application (BLA) for its ranibizumab biosimilar candidate (development name Xlucane) for treatment of retinal disorders.

Xbrane will work closely with the agency to submit as quickly as possible responses to the issues raised, which relate primarily to the reference standard and pre-approval inspections of manufacturing partners' sites.

On the reference standard that will be used for release of the product for the US market, FDA requested a tighter specification on one analytical method. Xbrane is confident of being able to resolve this issue.

Regarding FDA observations following pre-approval inspections, Xbrane will continue to work closely with its partners to implement the proposed improvements provided in the responses to the inspections performed by FDA. To date, FDA has not requested re-inspections of any sites.

To further clarify, FDA has not requested any additional clinical trials nor any further studies to demonstrate biosimilarity.

Xbrane will request a meeting with FDA, expected to be held within 30 days from request, to clarify further requirements related to above issues and will after that announce a planned date for resubmission of the BLA.

By reason of the news, Xbrane invites to a webcast Monday April 22nd, at 14.00 CET

If you wish to participate via audiocast please use the link below. Via the audiocast you are able to ask written questions.
https://ir.financialhearings.com/xbrane-biopharma-press-conference-april-2024

If you wish to participate via teleconference please register on the link below. After registration you will be provided phone numbers and a conference ID to access the conference.
https://conference.financialhearings.com/teleconference/?id=5006147

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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 2024-04-21 17:30 CEST.

Attachments

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