Xbrane Biopharma AB announces that partner STADA's Marketing Authorization Application for ranibizumab is submitted and validated by European Medicines Agency

Xbrane Biopharma AB (publ) ("Xbrane" or "the Company") (Nasdaq Stockholm: XBRANE) today announces that a Marketing Authorization Application (MAA) for biosimilar ranibizumab submitted by its co-development and commercialization partner, STADA Arzneimittel AG, has been validated by the European Medicines Agency (EMA).

Submission took place on September 9th and validation by EMA was communicated today. The EMA validation confirms that the application is sufficiently complete to begin a formal review process. The Company anticipates an EMA review for the biosimilar candidate, which was developed under the Xlucane™ name, will be according to standard timelines.

Xlucane™ is a biosimilar candidate to Lucentis® (ranibizumab), a VEGF-a inhibitor used in treatment of serious eye diseases, mainly wet age-related macular degeneration (wAMD) and diabetic macular edema (DME).

A trade name under which the biosimilar, if approved, will be marketed will be announced later in regulatory review process.

"This marks yet another important milestone for Xbrane. The team, together with our colleagues at STADA, have worked relentlessly over recent months in preparing this filing. This milestone also represents a potentially important advancement for patients and families living with wet age-related degeneration as our ambition is that Xlucane™ shall provide a more cost-efficient alternative to current treatments" says Xbrane CEO Martin Åmark.

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About Us

Xbrane Biopharma AB develops biological drugs based on a platform technology that provides significantly lower production costs compared to competing systems. Xbrane's leading product Xlucane™, a Lucentis® biosimilar candidate, addresses the € 10.4bn ophthalmic VEGFa inhibitor market. Marketing authorization of Xlucane™ is expected for the second half of 2022. Xbrane has additionally two biosimilar candidates in its pipeline targeting € 7.9bn in originator sales. 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.

Attachments

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