Xbrane announces that last patient has been enrolled into the pivotal phase III trial XPLORE

Xbrane Biopharma AB (publ) ("Xbrane Biopharma" or the "Company") has enrolled all the planned 580 patients in to XPLORE – the pivotal phase III trial for its leading biosimilar candidate Xlucane.

Xbrane Biopharma has as of today enrolled all the planned 580 patients in to the pivotal phase III trial XPLORE. Top-line data from XPLORE is expected to be communicated mid-2021 and filing of the Xlucane Marketing Authorization Application ("**MAA**") and Biologics License Application ("**BLA**") to European Medicines Agency ("**EMA**") and US Food and Drug Administration ("**FDA**") respectively will take place short thereafter.

XPLORE's objective is to demonstrate the equivalent efficacy and safety of the Company's leading product candidate Xlucane compared to Lucentis®. XPLORE includes 580 patients with wet age-related macular degeneration. Xbrane Biopharma will conduct an interim read-out from XPLORE when the last patient has reached month six of their treatment schedule and, as has been agreed with both EMA and FDA, file the MAA/BLA based on this interim read-out.

Taking into account the time required to finalise the clinical study report, filing of the MAA/BLA is expected to take place mid-2021. With an expected 12-month regulatory process upon filing, Marketing Authorization is expected in Europe and the US mid-2022 allowing for subsequent launch of Xlucane by Xbrane Biopharma's partners STADA Arzneimittel AG and Bausch + Lomb.

"We are pleased to be able to conclude enrolment to XPLORE and we are thankful to all the clinics and patients participating. This event is a major milestone for the company. The countdown for filing MAA/BLA now begins as the COVID-19 related enrolment risk has been eliminated." says Martin Åmark, CEO of Xbrane Biopharma.

Xbrane will host a webcast in connection with the release of the January-September 2020 interim report where the impact of this milestone and the timeline up to launch of Xlucane will be further discussed. The webcast will take place at 10:00 a.m. CET on 13 November 2020.

About Xlucane
Xlucane is a ranibizumab (Lucentis®) biosimilar candidate, a so-called VEGFa-inhibitor, intended to be used to treat a number of serious eye diseases: wet age-related macular degeneration (AMD), diabetic macular edema (DME), diabetic retinopathy (DR), as well as retinal vein occlusion (RVO). The market for VEGFa-inhibitors for ophthalmic use had sales of more than EUR 10 billion in 2019 and has grown by more than 10 percent per year in the past few years. A pivotal phase III study, XPLORE, is being conducted to demonstrate equivalence to Lucentis®. MAA/BLA for the product is expected to be submitted mid-2021. Xlucane will be commercialized by STADA across Europe, Middle East and select APAC countries and by Bausch + Lomb in North America.

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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 €10.4b ophthalmic VEGFa inhibitor market. Xlucane is in phase III and marketing authorization is expected mid-2022. Xbrane has additionally four biosimilars in its pipeline targeting €8.7b 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.

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 2020-11-11 17:30 CET.

Attachments

Xbrane announces that last patient has been enrolled into the pivotal phase III trial XPLORE