Xlucane is still on track towards regulatory approval ahead of Lucentis® patent expiration in EU July 2022 despite the impact of COVID-19 on the phase III-study Xplore

Xbrane Biopharma AB (publ) ("Xbrane" or the "Company") (Nasdaq Stockholm: XBRANE) today announces the following update on the ongoing phase III-study Xplore:

- As of today, Xlucane is still on track towards regulatory approval ahead of Lucentis® patent expiration in EU July 2022.
- Despite the global Corona crisis, Xplore remains open for recruitment of new patients and treatment for patients currently in the study.
- Xbrane is continuously taking all necessary steps to comply with the new COVID-19 guidance from local authorities and the European Medicines Agency ("EMA") and the US Food and Drug Administration ("FDA") with patient and clinic personnel safety as first priority.
- Currently approximately 60% of the planned 580 patients are recruited into Xplore.
- However, the rapid development of the COVID-19 pandemic makes forecasting of future recruitment rate challenging at this stage.

Xplore remains open for recruitment of new patients and treatment for patients currently in the trial

The COVID-19 pandemic is evolving rapidly and will have a significant impact on the global healthcare system. Xbrane will ensure the safety of Xplore study participants as well as the integrity of study data during the COVID-19 pandemic by following recommendations set by the EMA and the FDA.

Based on the circumstances below, Xbrane will maintain Xplore open for recruitment of new patients and continue treatment for all patients currently in the study.

- Patients in Xplore are treated for a critical eye-disease, age related macular degeneration, which if not treated leads to significant vision impairment and in worst case blindness and despite the risk of contamination of COVID-19 and local restrictions there is a desire from patients to be treated.
- Participation in Xplore does not lead to significantly more visits to a clinic than if the patients would receive standard treatment outside of a clinical trial.
- Over 50% of clinics are private eye-clinics located separately from general hospitals and therefore with lower risk of contamination of patients and clinic personnel in relation to patient visits.

Xbrane is supporting the clinics to take all measures possible to ensure patient safety in relation to visits. Out of the currently recruited patients approximately 42% are based in Eastern Europe, 20% in India, 10% in Israel, 6% in Russia and Ukraine, 14% in the US and 8% in Spain.

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Currently 355 out of 580 (approximately 60%) planned patients are recruited into Xplore and recruitment of new patients have taken place even during last two weeks. COVID-19 will inevitably result in a reduced recruitment rate compared to previously communicated pre-COVID-19 recruitment rate of 60-80 patients per month. Since the situation changes so rapidly any forecasting of recruitment rates in the coming months becomes challenging. Xbrane has previously agreed with the EMA and the FDA to submit Marketing Authorization Application ("MAA") /Biologics License Application ("BLA") on the basis of an interim read-out when last patient has reached month six in the treatment schedule. As long as Last Patient In to Xplore is recorded latest by end of third quarter 2020 and counting for a twelve month regulatory process, Xlucane is still on track towards approval ahead of Lucentis® patent expiration in EU July 2022.

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About Us

Xbrane is a commercial phase Swedish biopharmaceutical company that develop and produces biosimilars. Xbrane has a patented protein production platform for development of biosimilars and world leading expertise in biosimilars. Xbrane's headquarter is located in Solna outside of Stockholm and the company's in-house research and development facilities are in Sweden and Italy. Xbrane is listed at Nasdaq Stockholm since September 2019 with the ticker XBRANE. For more information please visit www.xbrane.com.

Attachments

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