

Xbrane successfully scales up Xdivane™ - biosimilar candidate to Opdivo® - and run an active partnering process

Xbrane Biopharma AB (publ) ("Xbrane" or "the Company") (Nasdaq Stockholm: XBRANE) announces that the company has achieved new production successes for Xdivane™, the company's biosimilar candidate to Opdivo® (nivolumab). Manufacturing for Xdivane™ is now taking place at the scale required for future commercialization and clinical trials.

"After 3 years of developing Xdivane™, we are proud to announce that we have successfully scaled up the production process to sufficient scale to commercialize and initiate clinical studies." says Siavash Bashiri, COO and Head of Biosimilars, Xbrane.

Xdivane™ is a biosimilar candidate to Opdivo® (nivolumab), an immuno-oncology PD-1 inhibitor used in the treatment of various types of cancer. The development program for Xdivane™ is on track for approval and launch at the time of US patent expiration in 2029. Clinical material will be produced this year, and clinical trials could be initiated first half of 2025.

"We have reproduced what we did in-house at pilot scale in industrial scale with selected production partner and thus demonstrated scalability for our patented platform technology for antibodies produced in mammalian cells with which we get a lower production cost compared to alternative systems.," says Siavash Bashiri.

Xbrane has worked actively with the development of Xdivane™ for the past three years, and by the end of 2024 Xbrane will have invested approximately USD25 million in the development program of the biosimilar candidate.

Xbrane is now running an active out-licensing process for Xdivane™ with the ambition to conclude a partnership in the third quarter of 2024. Xdivane™ is considered to be one out of few nivolumab biosimilar candidates in development for Europe and the US that are expected to be offered for out-licensing to commercialization partners.

The market for PD-1/PD-L1 inhibitors was estimated to USD45 billion in 2023 and is expected to surpass USD100 billion by 2028*. Opdivo® is expected to reach USD14 billion in sales by patent expiration**. The annual per patient drug cost is over USD100k. The ambition with Xdivane™ is to reduce that cost and enable treatment for more patients and realize important savings for the healthcare systems.

*)Mordor Intelligence

**)Evaluate Pharma

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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

Attachments

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