Xbrane provides update on its development portfolio

Xbrane Biopharma AB (publ) ("Xbrane" or the "Company") has lately received questions regarding its development programs BIIB801 and Xdivane™ and hence hereby provide an update.

BIIB801 – biosimilar candidate referencing Cimzia®

Xbrane has produced the first drug substance scale up batch of BIIB801 with its contract manufacturer and plan to produce GMP batches during Q4 2024 and Q1 2025. Intended to be used in an upcoming clinical trial. Xbrane expects to be able to sell the drug substance from the scale up batches to its commercial partner Biogen Inc. Xbrane expects to have finalized its development responsibilities of the program as per mid 2025 after which its partner Biogen takes over the responsibility for further development including clinical and regulatory development towards final potential marketing authorization. BIIB801 remains, as per Xbranes current knowledge, the only biosimilar candidate referencing Cimzia® under development globally. Cimzia® is a TNF inhibitor used in treatment of mainly rheumatoid arthritis and psoriasis with annual sales of about 2bEUR and a niche position in pregnant and breast-feeding women.

Xdivane™ – biosimilar candidate referencing Opdivo®

As previously communicated, Xbrane has successfully scaled up the drug substance production process and will produce GMP material intended for clinical trial during 2024. Xbrane has received positive feedback from European Medicines Agency (EMA) on its development program and is awaiting feedback from FDA during Q3 2024. Xbrane is working together with regulatory authorities in targeted territories to design a clinical development program that can support a future potential marketing authorization of the biosimilar candidate. In parallel Xbrane is running an active out-licensing process with the ambition to tie up a partner that can fully finance the clinical development as well as successfully commercialize the biosimilar candidate across main territories globally. Provided successful partnering during 2024 a clinical trial with Xdivane™ can be initiated H1 2025. Xdivane™ is a biosimilar candidate to Opdivo®, an immuno-oncology product with annual sales expected to reach USD 14 billion at patent expiry (Dec 2028 in US and 2030 in Europe)*. The market for PD-1/PD-L1 inhibitors was estimated to USD45 billion in 2023 and is expected to surpass USD100 billion by 2028**. The annual per patient drug cost is over USD 100 thousand. The ambition with Xdivane™ is to reduce that cost and enable treatment for more patients and realize important savings for the healthcare systems.

*)Evaluate Pharma
**) Mordor Intelligence

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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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