Xbrane provides update on the ongoing out-licensing of Xdivane™ (nivolumab biosimilar candidate) and XB003 (Cimzia® biosimilar candidate) and its financial position

As communicated on 1 August 2024 and given the previously communicated delay in FDA approval of Ximluci® and the unforeseen termination of the license agreement with Biogen, Xbrane Biopharma AB (publ) ("Xbrane" or the "Company") has initiated a process to out-license both Xdivane™ and XB003 for purposes of ensuring financing until envisioned positive operational cash-flow in Q2 2025. It has now become obvious that the company needs to finalize one of the above-mentioned license deals at satisfactory terms prior to the end of October 2024 to fulfill the Company's working capital requirements from beginning of November 2024 and onwards. The Company's Board of Directors and Senior Management believe this is feasible given the high level of interest in XB003, due to the program's uniqueness, and for Xdivane™, a revised streamlined clinical development focusing on outside of US markets based on positive EMA feedback. Both out-licensing processes are being led by a highly regarded external biopharma licensing consultant. The Company's Board of Directors and Senior Management are fully committed and working relentlessly to resolve this and are also exploring other possible avenues to preserve shareholder value.

Ongoing out-licensing of XB003 (Cimzia® biosimilar candidate, previously known as BIIB801)

XB003 is, as per Xbranes knowledge, the only biosimilar candidate under development referencing Cimzia® globally. Cimzia® is a TNF inhibitor used in treatment of mainly rheumatoid arthritis and psoriasis with annual sales of about € 2 billion with a niche position in pregnant and breast-feeding women. Xbrane has developed XB003 based on its patented platform technology enabling high yield/low-cost production. Xbrane has made significant progress in the program lately, successfully scaling up the production process together with Xbranes selected contract manufacturer with confirmed analytical similarity to the reference product. The program is ready to initiate clinical trials during 2025. However, as communicated on 1 August 2024, the license agreement with Biogen Inc. was terminated due to a strategic revision by Biogen and Xbrane regained the full rights to the program. This was an unforeseen event, which significantly impacted the Company´s expected income during the coming 6-12 months. Xbrane immediately initiated an out-licensing process of the biosimilar candidate under an accelerated timeline. Initial discussions have been held with several interested parties, and the Company perceives a high level of collaboration interest around the program. The out-licensing process runs according to a strict established timeline with an envisioned license agreement to be signed at the latest by the end of October 2024. Given the high level of interest in the product, Xbrane believes that this timeline can be accommodated. Xbrane maintains its view that this is a unique program that would benefit patients and payors in form of a more affordable treatment option.

Ongoing out-licensing of Xdivane™ (Opdivo® biosimilar candidate)

Xdivane™ is one out of few Opdivo biosimilar candidates available for out-licensing that runs according to a timeline that would enable a launch upon patent expiry. Opdivo is a so called immune-oncology drug (PD1 inhibitor) used in treatment of different cancers, with sales of approx. 8 billion USD globally during 2023, expected to grow to 14 billion USD by 2028 (source: Global Markets). Sales outside of US was approx. 3,2 billion USD in 2023 or 40' % of the global sales and is expected to grow to more than 5 billion USD by 2028.

. Despite the size of the opportunity and the relatively low competition envisioned from other biosimilar candidates, out-licensing has proven more difficult than initially envisioned by the Company. Xbrane has had discussions with several potential partners regarding development collaborations for a long time, but the main challenge has been related to the high envisioned clinical budget for both a phase 1 and a phase 3 trial, as per current biosimilar development guidelines. Running clinical trials in oncology is more expensive than in other indications and the cost for procurement of the reference product for the comparator arm is significant. The Company is now seeking acceptance with regulatory authorities for a streamlined clinical development plan and has received positive feedback in this direction from EMA (European Medicines Agency: The positive EMA feedback came on the back of a highly similar analytical profile of Xdivane™ vs. the reference product across an extensive panel of analytical methods. Now the Company has a crucial upcoming meeting with the US FDA in mid-September 2024. If FDA requires a clinical development plan including a full phase 3 trial, the Company will target a development of the biosimilar candidate for outside US markets, since it now stands clear the Company will be unable, by itself or via partners, to finance a full phase 3 program. This impacts the out-licensing timeline of the program, and the Company hence currently refocus out-licensing discussions with companies interested in Europe and other key territories outside of US where current interest is greater than for a global transaction. Xbrane sees a positive business case for such streamlined focused development plan for the program and maintains its view that patients and payors would, given the high pricing of the reference product, significantly benefit from this biosimilar candidate in form of a more affordable treatment option.

Commercialization of Ximluci®

Growth in sales of Ximluci® in Europe doubled in Q2 2024 compared to the observed growth in previous quarters. This is much stronger than anticipated and impacts the profit-sharing income positively in Q2 2024. The Company is further working according to the previously communicated plan, a re-submission of the BLA to FDA in Q4 2024 as well as approval and launch of a pre-filled syringe in Europe during 2025.

Financial position

As communicated on 1 August 2024, positive operational cash-flow is now envisioned to be reached in Q2 2025 and maintained thereafter provided FDA approval of Ximluci® (proposed biosimilar referencing Lucentis®) in Q2 2025 but not including any potential income from XB003, Xdivane™ (proposed biosimilar referencing Opdivo®) or other programs. Further, as communicated on 1 August 2024, given the previously communicated delay in FDA approval of Ximluci® and the unforeseen termination of the license agreement with Biogen, Xbrane needs to successfully out-license both Xdivane™ and XB003 during the coming months to ensure financing until envisioned positive operational cash-flow in Q2 2025. It is now clear, that the Company needs to finalize one of the above-mentioned license deals at satisfactory terms prior to the end of October 2024 to fulfill the Company's working capital requirements from beginning of November 2024 and onwards. The Company's Board of Directors and Senior Management believe this is feasible given the high level of interest in XB003, due to the program's uniqueness, and for Xdivane™ a revised streamlined clinical development focusing on outside of US markets based on positive EMA feedback. The Company's Board of Directors and Senior Management are fully committed and working relentlessly to resolve this and are also exploring other possible avenues to preserve shareholder value.

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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

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 2024-08-12 08:10 CEST.

Attachments

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