Xbrane provides update from Scientific Advice with US FDA on Xdivane™ (Opdivo® biosimilar candidate)

Xbrane Biopharma AB (publ) ("Xbrane" or the "Company") has received scientific advice from the US Food and Drug Administration (FDA) on the development of its Opdivo® biosimilar candidate Xdivane™. FDA concurs with EMAs previous feedback, finding Xbranes proposed streamlined clinical development plan adequate to support a future Biologics License Application (BLA). Xbranes development plan includes a single clinical trial and reduces the clinical development budget with at least 60%, from approx. €120m to €50m or lower, vs. a traditional approach with separate phase 1 and phase 3 trials.

Xdivane™ is one out of few Opdivo® biosimilar candidates available for out-licensing on path to enable a launch upon Loss of Exclusivity in US in December 2028. Opdivo® is a so called immune-oncology drug (PD1 inhibitor) used in treatment of different cancers, with sales of approx. 8 billion USD globally in 2023 and expected to grow to 14 billion USD by 2028*.

As communicated on the 12th of August, the Company is seeking acceptance from regulatory authorities for a streamlined clinical development plan and has received positive feedback in this direction from EMA (European Medicines Agency). The Company has now received similarly positive feedback from the FDA in a recent Scientific Advice meeting. FDA concurs with EMAs feedback and find Xbranes proposed streamlined clinical development plan adequate to support a future BLA. Xbranes development plan includes a single clinical trial and reduces the clinical development budget with at least. 60% from approx. €120m to €50m or less**,** vs. a traditional approach with separate phase 1 and phase 3 trials. The clinical design also limits the number of patients having to be recruited and hence makes it feasible to finalize the trial in time to support submission of a BLA latest Q4 2027.

Given agreement with both EMA and FDA on a feasible clinical development plan, Xbrane now focus the program for a global market and target approval, aiming for launch in time for loss of exclusivity in the US (December 2028). This significantly increases the attractiveness of the program for potential commercialization partners. As previously communicated, Xbrane, supported by a reputable life science advisor, is running an active out-licensing process with multiple interested potential partners with the ambition to conclude the process within coming months.

*) Source: Global Markets

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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 2024-09-27 09:02 CEST.

Attachments

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