XBRANE PROVIDES UPDATE ON THE ONGOING OUT-LICENSING OF XDIVANE™ (NIVOLUMAB BIOSIMILAR CANDIDATE) AND XB003 (CIMZIA® BIOSIMILAR CANDIDATE) AND ITS FINANCIAL POSITION

Xbrane Biopharma AB (publ) ("Xbrane" or the "Company") is, as communicated on August 12th, actively seeking partners for its biosimilar candidates Xdivane™ and XB003. The company has reached agreement negotiation stage with Xdivane™ and received the first non-binding proposals on XB003. The company has, via agreed prolonged payment plans vs. main suppliers, extended the timing to end of November 2024 until when an agreement needs to be finalized to, via an expected upfront payment, fulfill the Company's working capital requirements.

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 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 during 2023, expected to grow to 14 billion USD by 20281. The program is de-risked as scale-up of the drug substance production process is completed to commercial scale, analytical similarity to the reference product demonstrated and scientific advice on a streamlined clinical development plan received from both EMA and FDA.

XB003 is a biosimilar candidate referencing Cimzia® - a € 2 billion TNF inhibitor used in treatment of mainly rheumatoid arthritis and psoriasis with a niche position in pregnant and breast-feeding women. Xbrane has developed XB003 basd on its patented platform technology enabling high yield/low-cost production and successfully scaled up the production process to clinical scale. Further has analytical similarity to the reference product been demonstrated and Scientific Advice with EMA and FDA on the clinical development plan expected in Q1 2025.

Xbrane is running an active out-licensing process for both Xdivane™ and XB003, with multiple interested potential partners involved, supported by a reputable life science advisor. The company has reached agreement negotiation stage with Xdivane™ and received the first non-binding proposals on XB003. Further, Xbrane has, via agreed prolonged payment plans vs. main suppliers, extended the timing until end of November 2024 when an agreement needs to be finalized to, via an expected upfront payment, fulfill the Company's working capital requirements. Xbranes board and management is optimistic, given the advanced stage of agreement negotiation, to be able to close a partnership with Xdivane™ before the end of November 2024.

Contacts

Martin Åmark, CEO
E: martin.amark@xbrane.com

Anette Lindqvist, CFO/IR
E: anette.lindqvist@xbrane.com

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 2024-10-21 08:00 CEST.

Attachments

XBRANE PROVIDES UPDATE ON THE ONGOING OUT-LICENSING OF XDIVANE™ (NIVOLUMAB BIOSIMILAR CANDIDATE) AND XB003 (CIMZIA® BIOSIMILAR CANDIDATE) AND ITS FINANCIAL POSITION