Xbrane to regain full rights to BIIB801, a proposed biosimilar referencing CIMZIA®

Xbrane Biopharma (publ) ("Xbrane" or the "Company") today announced they will regain full rights to BIIB801 following a decision by Biogen Inc.to terminate the commercialization and license agreement between the companies. All rights to the product will be reverted to Xbrane. An out-licensing process to identify a new partner has been initiated. BIIB801 is a preclinical monoclonal antibody fragment that is a proposed biosimilar referencing CIMZIA® (certolizumab pegol

BIIB801 is the only biosimilar candidate under development referencing Cimzia®

Xbrane has developed BIIB801 based on its patented platform technology enabling high yield production. The platform is especially well suited for antibody fragments expressed in *e-coli* host cells, which is the case for certolizumab, the active substance in Cimzia®. Thanks to this platform technology and the ability to reach the required production yield for a commercially viable biosimilar, BIIB801 is currently, as per Xbrane's 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. The production process of the biosimilar candidate is successfully scaled up together with Xbrane's selected contract manufacturer and production of clinical material is taking place during 2024 enabling initiation of clinical trial in 2025. Analytical similarity is demonstrated and initial scientific advice with both EMA and FDA has been held. The production process enabling the high yield is patented by Xbrane.

Xbrane regain full rights to BIIB801

Xbrane entered into a licensing agreement for BIIB801 with Biogen Inc. in February 2022. Under the terms of the agreement Biogen paid a non-refundable upfront payment of USD 8 million. Biogen has indicated to Xbrane that the termination relates to a recent strategic review. All rights granted to Biogen under the agreement will be terminated and hence the full rights to the program will be retained by Xbrane.

A structured out-licensing process initiated

Xbrane has over the last 12 months received significant inbound interest in the program from potential commercialization partners in case the rights would be regained. Xbrane has initiated a structured out-licensing process with the ambition to find a new development and commercialization partner. Given the program´s uniqueness, Xbrane is optimistic in the possibilities of being successful in this process under an accelerated timeline.

Impact on Xbranes financial position

Xbrane has previously communicated a target to reach positive operational cash-flow in Q1 2025. 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 BIIB801, XdivaneTM (proposed biosimilar referencing Opdivo®) or other programs. Xbrane communicated in connection with the rights issue in Q1 2024 that, provided successful execution of the business plan, including timely FDA approval for Ximluci® and a secured partnership for Xdivane™, the net proceeds from the rights issue would fulfill the Company's working capital requirement until Q1 2025. 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 XdivaneTM and BIIB801 during coming months to ensure financing until envisioned positive operational cash-flow in Q2 2025. Xbrane is currently in advanced negotiations regarding out-licensing of XdivaneTM and believes an accelerated out-licensing process for BIIB801 is possible given the uniqueness of the program.

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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 2024-08-01 08:58 CEST.

Attachments

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