Xbrane Biopharma announces product portfolio update with a new full strategic focus on biosimilars

The board of directors of Xbrane Biopharma (publ.) (“Xbrane” or the Company) has decided to shift strategic focus in the Company’s product pipeline to biosimilars. As Xbranes leading biosimilar Xlucane (ranibizumab (Lucentis®) biosimilar) moves into the pivotal clinical trial, Xbrane is accelerating development of Xcimzane (certoizumab pegol (Cimzia®) biosimilar) and Xoncane (pegaspargase (Oncaspar®) biosimilar) and will initiate development of two additional biosimilars on biologics with patent expiration 2026-2028. As a consequence of the Company’s strategic focus of capital and resources on biosimilars, further development of generic long acting injectables beyond Spherotide (generic long acting triptorelin) will only be pursued if additional resources become available.

Strategic focus on biosimilars
The co-development agreement for Xlucane entered with STADA Arzneimittel AG in July 2018 validated the quality and commercial viability of Xbranes technological platform and capability in biosimilar development. This combined with the inherent attractiveness, particularly considering the favourable risk/reward profile, of biosimilars, the board of directors of Xbrane has decided to dedicate the absolute majority of the Company’s development resources to biosimilars going forward. As a consequence of this, further development of generic long acting injectables beyond Spherotide will only be further pursued if additional resources become available, either internally or via strategic partnerships. This concerns specifically generic long acting risperidone, leuprolide, exenatide and octreotide.

Accelerated development of Xcimzane and Xoncane
Xbrane is accelerating the development of Xcimzane (certoizumab pegol (Cimzia®) biosimilar), and Xoncane (pegaspargase (Oncaspar®) biosimilar. Cimzia® is a TNF inhibitor approved for treatment of rheumatoid arthritis, psoriasis and Crohn’s disease with annual sales of €1.4 billion in 2017. The main patents are set to expire in 2024 in Europe and the US. Oncaspar® is used in the treatment of acute lymphocytic leukaemia, a disease affecting especially children. The product had annual sales of approx. USD 0.2 billion in 2017. Xbrane is currently, in the development of both Xcimzane and Xoncane, leveraging the Company’s patented E.coli based protein expression technology with significant yield and cost advantage compared to standard systems.

“As Xlucane moves into the clinical trial we are now able to dedicate more development resources to Xcimzane and Xoncane programs. We are excited about these programs as we see very limited competition and an opportunity to bring the first biosimilars to market. Further, both products are well suited for our patented protein expression technology that will provide us with a cost advantage.” says Martin Åmark, CEO Xbrane.

Initiating development of two additional biosimilars
Xbrane is in the process of expanding its technological platform and capabilities to development of mammalian cell-based biosimilars. Xbrane do this by leveraging its unique technology, competence and know-how already established, in combination with strategic partnerships and few key recruitments. Based on this expanded platform Xbrane is initiating development of two additional biosimilars on biologics with patent expiration 2026-2028.

“In our ambition of becoming a world leading biosimilar developer it is critical for us to expand our technological platform into mammalian cell-based products. We do this leveraging our unique technological platform and capabilities already established in combination with select strategic partnerships and recruitments. We see multiple attractive opportunities to address and we have decided
to develop two biosimilars on two fast growing biologics with a current combined global sale well above USD 5 billion with patent expiration 2026-2028. Now is the right time to initiate development of biosimilars to these biologics and we see the opportunity to be ahead of the game and to be amongst the first to launch.” says Anders Tullgren, Chairman of the Board of Xbrane.

Initially the development of the biosimilars in the pipeline is done with freed up resources from Xlucane development, however long-term successful development requires that sufficient capital can be raised in the market.

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About Xbrane
Xbrane is a commercial phase Swedish biopharmaceutical company specialized in biosimilars. Xbrane has a patented protein production platform for development of biosimilars and world leading expertise in biosimilars. Xbrane’s headquarter is located in Solna outside of Stockholm and the company’s in-house research and development facilities are in Sweden and Italy. Xbrane is listed at Nasdaq First North since February 3rd, 2016 under the name XBRANE and Avanza Bank AB is Xbrane’s certified adviser. For more information see www.xbrane.com.

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