



Press release

Xbrane and STADA enter into a co-development agreement for Xlucane

Bad Vilbel, July 12, 2018 – Xbrane Biopharma AB (“Xbrane”) and STADA Arzneimittel AG (“STADA”) have entered into a co-development agreement for Xlucane, a Lucentis® (ranibizumab) biosimilar.

About the agreement

The collaboration between Xbrane and STADA is based on a co-development agreement, meaning that the companies will equally contribute to development expenses and share profits from commercialization in a 50/50 split. To enter into this agreement, STADA will make an upfront payment to Xbrane of EUR 7.5 million. In close consultation and agreement with STADA, Xbrane will be responsible for the development of the product until completion of the marketing authorization applications to EMA (European Medicines Agency) and FDA (US Food and Drug Administration), as well as for supply of the finished pharmaceutical product. STADA will hold the marketing authorizations and will be responsible for sales and marketing of the product across all territories included in the agreement. The co-development agreement covers Europe, the US and a variety of MENA and APAC markets.

The road ahead

Next step in the development of Xlucane is the initiation of the pivotal phase I/III clinical trial. Xbrane has agreed on the study design with EMA and FDA and has selected a leading Contract Research Organization to conduct the study, which is aimed to demonstrate similarity vs. Lucentis®. The study will involve a large number of wet AMD (age-related macular degeneration) patients across 16 countries.

STADA CEO Dr. Claudio Albrecht says: “The collaboration with Xbrane, with its team of very experienced development experts, is a great opportunity for STADA to accelerate the expansion of our biosimilar portfolio and to strengthen our market position in this segment.”

Executive Board: Dr. Claudio Albrecht (CEO) / Mark Keatley / Miguel Pagan
Supervisory Board Chairman: Dr. Günter von Au



Martin Åmark, CEO of Xbrane, says: "We are very excited to enter into this co-development partnership with STADA. STADA is a strong player and has long experience in distributing and marketing biosimilars. We could not have found a better partner to help develop and commercialize Xlucane."

Anders Tullgren, Chairman of the Board of Directors at Xbrane, comments: "The co-development deal with STADA is a significant achievement and opportunity for Xbrane which confirms Xbrane's unique capabilities and competencies in biosimilar development. The deal will contribute significant funding and expertise for the development and commercialization of Xlucane and will help to accelerate the development of our pipeline of biosimilars as well as the transformation of Xbrane into a major player in the fast-growing global biosimilars market."

About Xlucane

Xlucane is a biosimilar to the VEGFa inhibitor ranibizumab (Lucentis®). Lucentis® is used in treatment of several eye diseases, mainly neovascular age-related macular degeneration (wet AMD), diabetic related macular oedema (DME) and retinal vein occlusion (RVO). All these conditions cause deteriorating vision and, if untreated, can lead to blindness. VEGFa inhibitors bind to the growth factor VEGFa and thereby inhibit growth of abnormal blood vessels causing the deteriorating vision amongst patients. Xbrane estimate global prevalence of targeted indications to approximately 60 million, out of which 1.5-2.5 million receive treatment with VEGFa inhibitors. Hence, there is a significant undertreatment of these eye diseases, preliminary driven by the high cost of the originator products, creating further opportunities for lower priced biosimilars. During 2017 Lucentis® global sales amounted to €2.8 billion.

About STADA Arzneimittel AG

STADA Arzneimittel AG is a publicly-listed company with headquarters in Bad Vilbel, Germany. The company focuses on a three-pillar strategy consisting of generics, non-prescription OTC products and specialty pharmaceuticals, biosimilars in particular. Worldwide, STADA is represented in about 30 countries with roughly 50 subsidiaries. Branded products such as Grippostad and Ladival are among the highest selling in their product categories in Germany. In financial year 2017, STADA achieved adjusted Group sales of Euro 2,255.3 million, adjusted earnings before interest, taxes, depreciation and amortization (EBITDA) of Euro 433.9 million and adjusted net income of Euro 195.6 million. As per December 31, 2017, STADA employed 10,176 people worldwide.

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About Xbrane

Xbrane Biopharma AB is a biotechnology company which develops, manufactures and produces commercial biosimilars. Xbrane has a patented protein production platform for development of biosimilars and world-leading expertise within biosimilars. Xbrane's head quarter is located in Solna, outside Stockholm, and the company has research and development facilities in Sweden and in Italy. Xbrane has been listed on Nasdaq First North since 3 February 2016 with the ticker XBRANE. Avanza Bank AB is Xbrane's Certified Adviser. For more information see www.xbrane.com.

For further information, please contact:

STADA Arzneimittel AG
Media Relations
Stadastrasse 2–18
61118 Bad Vilbel – Germany /
Phone: +49 (0) 6101 603-165
E-Mail: press@stada.de
Or visit us on the Internet at www.stada.com

Xbrane Biopharma AB
Martin Amark
Chief Executive Officer
Mobile: +46 (0) 763-093 777
E-Mail: martin.amark@xbrane.com

Susanna Helgesen,
CFO & Head of Investor Relations
Mobile: +46 (0) 708-278 636
E-Mail: susanna.helgesen@xbrane.com

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