Xbrane and STADA partner with Valorum Biologics to commercialize ranibizumab biosimilar candidate in the US

Partners Xbrane and STADA license US commercial rights to ranibizumab to Valorum, a biosimilar commercialization specialist established by industry leaders to more efficiently sell and market biosimilars in the US. Valorum will pay a license fee of up to US$45 million, plus royalties on net product sales. The three partners are committed to bringing the ranibizumab biosimilar candidate to the US market as soon as possible, thereby fostering competition that can reduce costs and increase patient access to biological medicines for serious eye conditions

Stockholm/Bad Vilbel/New York – May 10th, 2024 – Partners Xbrane Biopharma AB ("Xbrane") and STADA have entered into an exclusive licensing agreement with US biosimilars specialist Valorum Biologics for their ranibizumab biosimilar candidate.

Under the terms of the agreement, leading Swedish biosimilar developer Xbrane and Germany-based specialty pharma, generics and consumer healthcare company STADA are responsible for completing the regulatory approval process for the ranibizumab candidate, which was developed under the Xlucane name. Xbrane is responsible for commercial manufacturing and supply.

Valorum will be responsible for sales, marketing and all other commercialization efforts in the United States following regulatory approval of the product, which is expected to be marketed under the Lucamzi™ brand name. Valorum is a biosimilar commercialization specialist founded by several veteran leaders across the industry, including Mark Santos, Joe DePinto and Mike Cunningham, past presidents of AmerisourceBergen, Cardinal Health and General Manager of McKesson, respectively. The team brings unparalleled experience and established networks across the US pharmaceutical market. Valorum is focused on best-in-class commercialization of biosimilars in the US to improve access, reach and cost savings for the healthcare system. Valorum has built a team specialized in commercializing biosimilars in the US and will be well positioned to maximize the potential of the ranibizumab candidate, which is currently marketed by STADA in 16 European countries under the Ximluci® brand name. The team has collectively launched several multi-billion dollar pharmaceutical products within large pharmaceutical organizations such as Johnson & Johnson, Merck and Roche.

"*We believe Valorum is the ideal partner for us to commercialize ranibizumab in the US. We share the same entrepreneurial spirit and mindset*," said Martin Åmark, CEO of Xbrane Biopharma. "*Success of this launch will be as important and defining for Valorum as for us, and hence we are convinced the product will get the full attention it requires. Further, we are convinced that Valorum with its unparalleled team with vast experience and network across the US will be able to commercialize biosimilars, including Lucamzi ™, highly effectively.*"

"*The Valorum team's expertise and experience with marketing, selling and distributing biosimilars in the complex US market will be invaluable to delivering value to patients, healthcare professionals, payers and all three partners in this alliance,*" stated STADA's Head of Global Specialty, Bryan Kim.

"*We are very excited to launch Lucamzi ™in the US. We see great potential for another biosimilar to Lucentis® and expect to build upon our team's proven track record of commercial success and capture a meaningful market share through our expertise across specialty markets in the US,*" **said** Par S. Hyare, CEO of Valorum. "*Beyond taking market share from Lucentis® and ranibizumab biosimilars, we believe there is a meaningful opportunity to transition current usage of other anti-VEGF agents, including spontaneous unapproved use of bevacizumab which accounts for approximately 40% of all units sold in this market, to cost-efficient alternatives such as Lucamzi.™*"

Ranibizumab is an anti-VEGF (vascular endothelial growth factor) drug for treating retinal vascular disorders, which are a leading cause of blindness globally. Nearly 20 million people in the US are living with some form of AMD, of whom an estimated 18 million are aged 40 years and older*. Estimated direct healthcare costs of visual impairment due to AMD in the US, Canada, and Cuba (WHO subregion AMR-A) are approximately US$98 billion, while direct healthcare costs globally linked to AMD total US$255 billion**.

If approved by the US Food and Drug Administration (FDA), the biosimilar candidate is expected to provide a valuable, cost-efficient alternative to existing treatments and hence increase access and reduce associated healthcare costs in the US.

Under the terms of the licensing agreement, Valorum will pay a license fee of up to US$45 million, which will include regulatory approval and sales-related milestones. This fee, plus royalties paid by Valorum on net sales of the product, will be shared equally by STADA and Xbrane. Under a separate agreement, Xbrane will supply the product to Valorum at a double-digit mark-up over cost of goods sold (CoGS).

Stifel served as exclusive financial advisor to Valorum on this transaction.

*) Age-Related Macular Degeneration: Facts & Figures | BrightFocus Foundation
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By reason of the news, Xbrane invites to a webcast Monday May 13th, at 15.00 CET
If you wish to participate via audiast please use the link below. Via the audiocast you are able to ask written questions.
https://ir.financialhearings.com/xbrane-biopharma-pressconference-may-2024
If you wish to participate via teleconference please register on the link below. After registration you will be provided phone numbers and a conference ID to access the conference. You can ask questions verbally via the teleconference.
https://conference.financialhearings.com/teleconference/?id=5006309

About STADA Arzneimittel AG
STADA Arzneimittel AG is headquartered in Bad Vilbel, Germany. The company focuses on a three-pillar strategy consisting of consumer healthcare products, generics and specialty pharma. Worldwide, STADA Arzneimittel AG sells its products in approximately 115 countries. In financial year 2023, STADA achieved group sales of EUR 3,734.8 million and reported earnings before interest, taxes, depreciation and amortization (EBITDA) of EUR 802.1 million. As of 31 December 2023, STADA employed 11,667 people worldwide.

About Valorum Biologics
Valorum provides best-in-class execution for the regulatory approval, launch and commercialization of biosimilars in the U.S. The Valorum team brings unparalleled experience and established networks across the U.S. pharmaceutical market and is focused on optimizing commercialization in order to improve access, reach and cost savings for the healthcare system.

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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 2024-05-10 08:00 CEST.

Attachments

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