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Xbrane Pulls In US Ranibizumab Partner After FDA Disappointment

License Fee Of Up To $45m Agreed, To Be Split Between Xbrane And Stada

by Dean Rudge

Xbrane Biopharma's recent CRL for its proposed US biosimilar to Lucentis has not prevented the Swedish company from announcing a successor to Bausch + Lomb to partner on the biosimilar's US marketing and commercialization.

Xbrane Biopharma has come good on its recent promise that a US marketing partner for its proposed biosimilar to Lucentis (ranibizumab) was within reach, despite the setback last month of a US Food and Drug Administration complete response letter.

The Swedish biosimilars developer and its partner Stada have formed a partnership with US biosimilars specialist Valorum Biologics, handing over responsibility for sales, marketing and all other commercialization efforts in the US following regulatory approval of the product.

Under the terms of the licensing agreement, Valorum will pay a license fee of up to $45m, 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," the Swedish firm noted. "Under a separate agreement, Xbrane will supply the product to Valorum at a double-digit mark-up over cost of goods sold."

Meanwhile, for the first time Xbrane has confirmed the US trade name for its proposed Lucentis biosimilar: Lucamzi.

Previously, the biosimilar candidate was referred to during the clinical trial phase as Xlucane. In Europe, it is approved and sold under the name Ximluci. (Also see "*Stada And Xbrane Gain EU*

All-Clear For Ranibizumab Biosimilar" - Generics Bulletin, 14 Nov, 2022.)

Swedish financial services firm Redeye acknowledged that, given the lack of specifics, it is unknown how much of the $45m is tied to regulatory or potential upfront payments.

"Nonetheless, following our call with the CEO this morning, we believe it is reasonable to assume that the majority is sales-related and a reasonable assumption that approximately $15m relates to regulatory and upfront payments. Our estimate is upfront payments of around $5m and a regulatory milestone of around $10m, with Xbrane being entitled to 50%."

Meanwhile, Redeye pointed out that the separate supply agreement was something of a boon, given that a similar arrangement with Stada for the biosimilar sees Xbrane sell it to the German firm at cost.

Launch In H1 2025 Possible?

Xbrane had been on the hunt for a new US commercialization partner since last July, when eye-disease specialist Bausch + Lomb exited its arrangement with Xbrane and Stada via mutual consent. (Also see "*Xbrane And Stada Seek Fresh Ranibizumab Partner In North America*" - Generics Bulletin, 26 Jul, 2023.)

Bausch + Lomb's exit from the project came just three months after Xbrane had refiled its ranibizumab biosimilar with the FDA – that filing eventually leading to a CRL that was disclosed by Xbrane last month.

In the latest knockback for Xbrane, the FDA pulled the firm's biologics license application up for issues related primarily to the reference standard and pre-approval inspections of manufacturing partners' sites (*see sidebar*).

On the other hand, the FDA did not request any additional clinical trials nor any further studies to demonstrate biosimilarity, nor did it request re-inspections of "any sites."

In response to the news, Xbrane has assembled a task force of "very experienced team members," both from the firm and also with "external

Xbrane Assembles The Troops As FDA Says No To Lucentis Biosimilar

By Dean Rudge

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Xbrane Biopharma was riding the crest of a wave with the EU launch of its biosimilar to Lucentis, following years of toil and investment. However, plans to roll out the product in the US will have to be pushed back – likely – into the middle of 2025, following a US FDA complete response letter.

Read the full article here

expertise," while promising to "work closely with the agency to submit as quickly as possible responses to the issues raised."

Redeye suggested that "a reasonable base case estimate would be that the new BsUFA date could span anywhere from six-to-12 months from today, which to us implies a potential first half 2025 launch in the US."

Who Are Valorum Biologics?

Valorum Biologics was co-founded in 2021 by its current chairman and CEO Par Hyare, after his former employer Sunesis Pharmaceuticals merged with Viracta Therapeutics. The firm's management team includes chief development officer Judy Fox, also formerly of Sunesis.

With offices in New York City, the firm is a "biosimilar commercialization specialist," according to Xbrane; also 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," Xbrane commented.

Martin Åmark, CEO of Xbrane, added: "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."

Hyare commented that he saw "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."

"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."