Press release

STADA and partner Xbrane advance biosimilar ranibizumab candidate

- Primary endpoint met in pivotal 'Xplore' ranibizumab comparability trial; regulatory submissions in EU and US planned during second half of 2021
- If approved, ranibizumab would take STADA's biosimilars portfolio into the multi-billion euro ophthalmics sector
- STADA's Global Head of Specialties, Bryan Kim: "We welcome this important step towards bringing a high-quality, cost-effective treatment option to ophthalmologists and their patients."

Bad Vilbel, 29 June 2021 – STADA and its biosimilar development partner Xbrane Biopharma have announced that their ranibizumab biosimilar candidate met its primary endpoint in a pivotal comparability trial involving 583 patients. On the basis of these six-month interim results from the Phase III-type 'Xplore' clinical trial, the two partners anticipate submitting a Marketing Authorization Application (MAA) to European Medicines Agency (EMA) and a Biologics License Application (BLA) to US Food and Drug Administration (FDA) during the second half of 2021.

In the randomized, double-masked, multi-center study, the ranibizumab biosimilar candidate met the primary endpoint demonstrating equivalent efficacy in BCVA (Best Corrected Visual Acuity) at Week 8 of treatment compared to the reference biologic, Lucentis®. Furthermore, the interim analysis of six-month data demonstrated that the biosimilar has similar pharmacokinetic, safety and immunogenicity profile compared to Lucentis®, a VEGF-α inhibitor used in treatment of serious eye diseases, mainly wet age-related macular degeneration (wAMD) and diabetic macular edema (DME)[1].

[1] https://xbrane.com/en/mfn_news/xlucanetm-meets-the-primary-endpoint-in-the-pivotal-phase-iii-trial-with-xlucanetm-regulatory-submission-in-eu-and-us-planned-for-second-half-of-2021/

Under the terms of a co-development agreement entered into in July 2018 for a biosimilar of Lucentis®, STADA and Xbrane will equally contribute to development expenses and share profits from commercialization. STADA will hold any granted marketing authorizations and will be responsible for sales and marketing of the product in Europe. Bausch + Lomb, the commercialization partner of STADA and Xbrane, will be responsible for marketing the ranibizumab biosimilar in North America. STADA and Xbrane are currently evaluating commercialization options, including regional partnerships, for the rest of the world.

“We welcome this important step towards bringing a high-quality, cost-effective treatment option to ophthalmologists and their patients,” commented Bryan Kim, STADA’s Global Head of Specialties. “With ranibizumab, STADA’s growing biosimilars presence would extend beyond oncology, nephrology, osteoporosis and autoimmune indications into the multi-billion-euro eyecare market. We look forward to continuing to work closely with our partner Xbrane on applying for regulatory approval of our biosimilar candidate in major markets.”

“Ranibizumab represents a key opportunity in STADA’s extensive biosimilars pipeline covering major disease areas such as ophthalmology, oncology and autoimmune conditions through our go-to-partner strategy,” STADA CEO Peter Goldschmidt pointed out. “Becoming a leading European supplier of biosimilars this decade will play an essential role in our roadmap for Specialty Pharmaceuticals, one of three strategic pillars for STADA alongside Generics and Consumer Healthcare.”

About STADA Arzneimittel AG

STADA Arzneimittel AG is headquartered in Bad Vilbel, Germany. The company focuses on a three-pillar strategy consisting of generics, specialty pharma and non-prescription consumer healthcare products. Worldwide, STADA Arzneimittel AG sells its products in approximately 120 countries. In financial year 2020, STADA achieved group sales of EUR 3,010.3 million and adjusted earnings before interest, taxes, depreciation and amortization (EBITDA) of EUR 713.3 million. As of 31 December 2020, STADA employed 12,301 people worldwide.

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