Press release

STADA and Xbrane secure EU approval for Ximluci® (ranibizumab) biosimilar referencing Lucentis®

- European Commission grants pan-EU marketing authorization for Ximluci® biosimilar referencing Lucentis® (ranibizumab)
- Paves way for European launch of Ximluci® early in 2023
- The partnership combines Xbrane's patented protein-expression system and Europe-based production platform with STADA's experienced clinical salesforce and key-account management teams, 125-year heritage and extensive sales and marketing expertise throughout Europe

Bad Vilbel; Solna – 11 November 2022 – STADA Arzneimittel AG and Xbrane Biopharma AB (Nasdaq Stockholm: XBRANE) announce that the European Commission has granted a marketing authorization for Ximluci® (ranibizumab), a biosimilar candidate referencing Lucentis®. This follows the positive opinion issued by the European Medicines Agency's (EMA's) Committee for Medicinal Products for Human Use (CHMP) in September 2022.

The centralized marketing authorization for Ximluci® 10 mg/ml solution for injection is held by STADA and is valid in all 27 European Union member states, as well as in Iceland, Norway and Liechtenstein. The partners are preparing for launches in selected European markets early in 2023.

In July 2018, STADA and Xbrane entered into an agreement under which the two companies are jointly responsible for development and for manufacturing the finished product. STADA holds the marketing authorizations and the commercial rights to the biosimilar across all

territories included in the agreement, which covers Europe, the US, several countries in the Middle East and North Africa (MENA) region, and selected Asia-Pacific (APAC) markets.

The partnership combines Xbrane's patented protein-expression system and Europe-based production platform with STADA's experienced clinical salesforce and key-account management teams, 125-year heritage, and extensive sales and marketing expertise throughout Europe as a top-four player in both generics and consumer healthcare.

Ximluci® is an anti-VEGF (vascular endothelial growth factor) for the treatment of retinal vascular disorders, which are a leading cause of blindness globally. Ximluci® has been approved in the European Union (EU) for the treatment of wet age-related macular degeneration (wet AMD), diabetic macular oedema (DME), diabetic retinopathy (PDR), retinal vein occlusion (RVO) and visual impairment due to choroidal neovascularization (CNV) in adults. Wet AMD affects an estimated 7 million people in Europe, with around 500,000 new patient incidences every year.[1]

Ranibizumab is the sixth biosimilar approved within STADA´s Specialty Care portfolio, joining adalimumab, bevacizumab, epoetin zeta, pegfilgrastim and teriparatide.

"Having already successfully launched five biosimilars," commented STADA CEO Peter Goldschmidt, "we are excited to take our rapidly expanding Specialty Care portfolio into an important and growing therapeutic category – ophthalmology. This product authorized through STADA's strategic partnership with Xbrane will help to increase patient access to biological treatments and optimize use of healthcare resources."

[1] Prevalence and incidence of age-related macular degeneration in Europe: a systematic review and meta-analysis | British Journal of Ophthalmology (bmj.com)

"We are proud to have worked with STADA to take this molecule, developed under the Xlucane™ name, from cell-line development to approval and manufacturing via our patented expression system in Europe," stated Martin Åmark, CEO of Xbrane. "Clinicians can prescribe Ximluci® with confidence of producing comparable clinical outcomes to the reference product, Lucentis®, based on extensive comparative quality studies and clinical data."

The marketing authorization for Ximluci® was based on a comprehensive comparative analytical assessment and a Phase 3 clinical study that demonstrated equivalent efficacy and comparable safety to the reference product Lucentis®. The Phase 3 clinical study involved 580 patients with wet age-related macular degeneration. The primary endpoint of the study was the change in best corrected visual acuity (BCVA) at week 8 compared to the baseline. This was met, as the adjusted treatment differences between the two products were within the predefined equivalence margin.

The market for anti-VEGFs for the treatment of retinal disorders in Europe generated sales of approximately €4 billion in 2021 and grew by 8% per year on average between 2019 and 2021. A large proportion of this market was accounted for by ranibizumab, as well as aflibercept, which also forms part of STADA's current biosimilars pipeline which covers ophthalmology, oncology and autoimmune candidates.

About STADA Arzneimitttel AG
STADA Arzneimittel is headquartered in Bad Vilbel, Germany. The company focuses on a three-pillar strategy consisting of generics, specialty pharma and consumer healthcare products. Worldwide, STADA sells its products in approximately 120 countries. In financial year 2021, STADA achieved group sales of EUR 3,249.5 million and reported earnings before interest, taxes, depreciation and amortization (EBITDA) of EUR776.5 million. As of 31 December 2021, STADA employed 12,520 people worldwide.

About Xbrane
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 53 billion in estimated annual peak sales of the respective reference product. The lead candidate Ximluci® has recently been granted market authorization approval in Europe will be launched during the first quarter 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

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