STADA and Xbrane obtain British approval for Ximluci® (ranibizumab) biosimilar referencing Lucentis®

- MHRA issues marketing authorization for Ximluci® biosimilar referencing Lucentis® (ranibizumab) in Great Britain
- STADA is preparing to launch Ximluci® in the UK during 2023
- The partnership benefits from Xbrane's patented protein-expression system and Europe-based production set-up, and STADA's considerable heritage supplying biosimilars and other specialty medicines in the UK

Bad Vilbel; Solna – 16 January 2023 – STADA Arzneimittel AG and Xbrane Biopharma AB (Nasdaq Stockholm: XBRANE) announce that the UK's Medicines and Healthcare products Regulatory Agency (MHRA) has granted a marketing authorization for Ximluci® (ranibizumab), a biosimilar referencing Lucentis®. STADA is preparing to launch Ximluci in the UK during 2023.

Xbrane's contribution to the partnership includes a patented protein-expression system and Europe-based production set-up, while STADA brings considerable heritage supplying biosimilars and other specialty medicines in the UK.

"Considerable unmet need for biologic ophthalmic treatments exists in the UK and throughout Europe," commented Bryan Kim, STADA's Head of Specialty Care. "With almost 15 years' experience of supplying biosimilars, STADA looks forward to working with Xbrane, as well as with NHS and our commercial partners, to broaden patient access to ranibizumab and optimize use of healthcare resources in the UK."

"We are proud to have worked with STADA to take this molecule, developed under the XlucaneTM name, from cell-line development to approval and manufacturing, based on our patented expression system, in Europe," stated Martin Åmark, CEO of Xbrane.

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 UK for treating 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.

According to the UK's Macular Society, nearly 1.5 million people in the UK have macular disease. Age-related macular degeneration is the most common condition, generally affected people aged over 55. AMD is the biggest cause of sight loss in the UK, affecting more than 600,000 people. [1]

The British marketing authorization was granted via the EC Decision Reliance Procedure (ECDRP), whereby the MHRA relied on the decision taken by the European Commission (EC) on 9 November 2022 to issue a centralized marketing authorization for Ximluci® valid in all 27 European Union member states, as well as in Iceland, Norway and Liechtenstein[2]. The European Medicines Agency had determined Ximluci® to be highly similar to the reference product, Lucentis®, based on data showing comparable quality, safety and efficacy to Lucentis®.[3]

The British marketing authorization for Ximluci® 10 mg/ml solution for injection is held by STADA's Genus Pharmaceuticals subsidiary.

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.

#Ximluci® 10mg/ml solution for injection is subject to additional monitoring

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.

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[1] Macular conditions - Macular Society
[2] STADA and Xbrane secure EU approval for Ximluci® | STADA; » STADA and Xbrane secure EU approval for Ximluci® (ranibizumab) biosimilar referencing Lucentis®
[3] Ximluci: European Medicines Agency (europa.eu)

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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 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

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 2023-01-17 08:00 CET.

Attachments

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