STADA and Xbrane launch ranibizumab to support patient access in Europe

Ranibizumab biosimilar is being launched in major European markets. Ranibizumab is the first product brought to market through a strategic collaboration between STADA and Xbrane Biopharma AB (Nasdaq Stockholm: XBRANE) , marking Xbrane's first commercial launch and STADA's first co-development asset, in its growing biosimilars portfolio. Developed and manufactured solely in Europe, ranibizumab is the sixth biosimilar marketed in Europe by STADA, and the first to treat ophthalmologic conditions.

Bad Vilbel, Germany/Solna, Sweden: – For the estimated 400,000 people per year in the European Union (EU) who develop age-related macular degeneration (AMD) every year, their impairment to sight can have a substantial impact on their quality of life and emotional wellbeing. Whether it's enjoying the latest film in a cinema or finding one's car keys, life can be difficult with AMD. Indeed, AMD is the main cause of severe visual impairment and blindness in Europe*[1]*, generating an estimated treatment cost of €2.4 billion per year.

With the introduction of ranibizumab in several European countries, partners STADA Arzneimittel AG and Xbrane Biopharma AB are offering European patients a cost-effective option to treat visual impairment in all the adult indications of the reference biologic.

Shipments of the ranibizumab biosimilar, which is produced, filled, sterilized, and packaged entirely within Europe, have begun, and launch activities are underway.

The advent of biosimilar competition in Europe's ranibizumab market offers improved patient access through cost-effective biosimilars with comparable quality, safety and efficacy to the original reference biologic. Such competition has already generated considerable value for patients, physicians and healthcare systems in therapeutic areas including immunology and oncology. For example, biosimilar competition on filgrastim increased patient access in the European union by 44%.

STADA has a diverse portfolio of biosimilars in Europe across therapeutic areas encompassing immunology, oncology and bone health, building on a corporate heritage spanning more than 125 years of supplying high-quality consumer healthcare and generic medicines.

Ranibizumab is the sixth biosimilar launched within STADA's Specialty Care portfolio joining epoetin zeta, pegfilgrastim, teriparatide, bevacizumab and adalimumab and the first product developed through a strategic collaboration between STADA and Xbrane. Under this agreement, begun in July 2018, the partners are jointly responsible for development and for manufacturing the finished product, while STADA holds the marketing authorizations and commercial rights.

"Having already successfully launched five biosimilars," commented STADA CEO Peter Goldschmidt, *"we are delighted to be making ranibizumab available to ophthalmologists and their patients. This European-made biosimilar, developed through STADA's strategic partnership with Xbrane, will help to increase patient access to biological treatments and foster competition that contributes to the sustainability of healthcare systems throughout Europe."*

"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 *protein-expression system. Commercialization of our first biosimilar in Europe marks a major milestone in the evolution of our company,"* stated Martin Åmark, CEO of Xbrane.

As with the reference biologic, the ranibizumab biosimilar is supplied as a 2.3mg/0.23ml single-use vial for injection for intravitreal use. The vascular endothelial growth factor (VEGF) inhibitor has been approved in European Union, as well as in the UK, for the treatment of wet AMD, diabetic macular oedema (DME), diabetic retinopathy (PDR), retinal vein occlusion (RVO) and visual impairment due to choroidal neovascularization (CNV) in adults.

The EU marketing authorization 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. 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 *[2].*

[1] Li JQ, et al. Br J Ophthal. 2020;104:1077–1084
[2] European Medicines Agency (europa.eu)

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 120 countries. In financial year 2022, STADA achieved group sales of EUR 3,797.2 million and reported earnings before interest, taxes, depreciation and amortization (EBITDA) of EUR 884.7 million. As of 31 December 2022, STADA employed 13,183 people worldwide.

STADA information for journalists:
STADA Arzneimittel AG - Media Relations
Stadastrasse 2-18
61118 Bad Vilbel - Germany
Phone: +49 (0) 6101 603-165
Fax: +49 (0) 6101 603-215
E-Mail: press@stada.de
Or visit us on the Internet at www.stada.com/press

STADA information for capital market participants:
STADA Arzneimittel AG - Investor & Creditor Relations
Stadastrasse 2-18
61118 Bad Vilbel – Germany
Phone: +49 (0) 6101 603-4689
Fax: +49 (0) 6101 603-215
E-mail: ir@stada.de
Or visit us on the Internet at www.stada.com/investor-relations

Contacts

Martin Åmark, CEO
M: +46 76 309 37 77
E: martin.amark@xbrane.com

Anette Lindqvist, CFO/IR
M: +46 76 325 60 90
E: anette.lindqvist@xbrane.com

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® is granted market authorization approval in Europe and is 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 2023-04-03 07:00 CEST.

Attachments

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