STADA and Xbrane launch Ximluci® as ranibizumab biosimilar in Germany

- **With Ximluci®, STADA and Xbrane recently launched the first joint biosimilar on the German market**

- **Ximluci®, used for the treatment of neovascular diseases of the retina (nAMD, DME, PDR, RVO and CNV), is already the sixth biosimilar from STADA and thus an optimal addition to STADA's constantly growing biosimilars portfolio.**

- **Dr Martin Spatz, head of STADA's specialty business in Germany: "*We are very pleased to be able to offer German ophthalmologists and their patients Ximluci ®- an additional therapy option for the treatment of neovascular diseases of the retina with immediate effect.*"**

Bad Vilbel / Solna – STADA Arzneimittel AG (STADA) and Xbrane Biopharma AB (**Nasdaq Stockholm: XBRANE**) jointly present their new product Ximluci®, a ranibizumab biosimilar, for the market launch in Germany. Ximluci® aims to offer ophthalmologists and their patients a cost-effective alternative to the reference product and to provide a universal option for the treatment of certain retinal disorders caused by damage to the retina and particularly the macula (nAMD, DME, PDR, RVO and CNV) 1). As a biosimilar, Ximluci® offers comparable efficacy, safety and immunogenicity profile to the reference product2. Ximluci has already started shipping in some European countries such as Germany, while others are currently preparing for launch. For the launch in Germany, the product was presented at the congress of the Ophthalmological Academy Germany (AAD) in March 2023 in Düsseldorf. STADA was represented with a stand on Ximluci® and several information materials, such as a product trailer and brochures for trade visitors and patients in the industrial exhibition. The event was used to discuss the new treatment option with numerous interested physicians.

According to current figures, around 7.4 million people in Germany live with AMD, of which around 10-15% are affected by neovascular age-related macular degeneration (nAMD) 3). Due to the general demographic development in Germany, the number of people affected is likely to increase further in the future. The impairment of vision caused by AMD has a major impact on patients' quality of life and well-being. The development and competition of various ranibizumab biosimilars in the European market offers patients low-threshold access to cost-effective treatment options. Biosimilars are already being used as reliable therapy options in other therapeutic areas such as oncology and immunology without any loss of quality, effectiveness or safety profile. STADA already offers a wide-ranging biosimilar portfolio for the European market — so far in the therapeutic areas of oncology, immunology and osteology. As the sixth biosimilar, Ximluci® will now expand this portfolio to include the therapeutic area of ophthalmology.

Ximluci® is the first biosimilar developed as part of a strategic partnership between STADA and Xbrane entered in July 2018. According to the collaboration agreement, both partners are responsible for the development and manufacturing of the product, which takes place entirely in Europe, while STADA holds the market approvals and commercial rights to the product.

"We are very pleased to be able to offer German ophthalmologists and their patients with Ximluci ®- a cost-effective therapy option for the treatment of neovascular diseases of the retina (nAMD, DME, PDR, RVO and CNV) 4)," explains Dr. Martin Spatz, head of the STADA specialty business in Germany. "*With our ranibizumab biosimilar, together with our partner Xbrane, we are giving even more patients access to biological treatment alternatives and thus helping to relieve the burden on healthcare systems.*"

Ximluci® is offered as a 2.3 mg/0.23 ml vial for intravitreal injection in Germany. Ximluci® (ranibizumab) - a vascular endothelial growth factor (VEGF-A) inhibitor, is approved in the EU and UK not only for the treatment of neovascular (wet) age-related macular degeneration (nAMD) but also for the treatment of proliferative diabetic retinopathy (PDR), and for the treatment of visual impairment secondary to diabetic macular edema (DME), retinal vein occlusion (RVO), and choroidal neovascularization (CNV) in adults. The EU approval for Ximluci® is based on extensive analytical comparisons with the reference product and an extensive phase III clinical study, which showed equivalent efficacy, safety and immunogenicity profile of Ximluci® compared to the reference product. 4)

1 nAMD - neovascular (wet) age-related macular degeneration, DME - a visual impairment secondary to diabetic macular edema, PDR - proliferative diabetic retinopathy, RVO - a visual impairment secondary to macular edema a retinal vein occlusion (branch vein occlusion or central vein occlusion), CNV – a visual impairment as a result of choroidal neovascularization, XIMLUCI® technical information, as of: November 2022.

2 Chopra R, Lopes G. J. Glob Oncol. 2017;3(5):596.

3 Gutenberg health study by the University Medical Center Mainz

4 XIMLUCI® specialist information, as of: November 2022.

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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® is granted market authorization approval in Europe and was 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 2023-05-26 08:00 CEST.

Attachments

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