

Press Release // May 17, 2022

**United Kingdom Medicines and Healthcare Products Regulatory Agency (MHRA) grants Marketing Authorisation for Bioeq AG's Biosimilar for Lucentis®<sup>1</sup> to be commercialised by Teva as ONGAVIA®.**

Zug – Bioeq AG announces, that today the Medicines and Healthcare products Regulatory Agency (MHRA) has granted Marketing Authorisation (MA) in the United Kingdom (“UK”) for FYB201, a biosimilar to Lucentis® (ranibizumab). Teva Pharmaceutical Industries Ltd. will serve as the exclusive commercial partner and will market the biosimilar under the brand name ONGAVIA® throughout the UK.

Lucentis® is used in the treatment of age-related neovascular (wet) macular degeneration (nAMD) and other serious eye diseases like visual impairment due to diabetic macular oedema (DME), proliferative diabetic retinopathy (PDR), visual impairment due to macular oedema secondary to retinal vein occlusion (branch RVO or central RVO) and visual impairment due to choroidal neovascularization (CNV). It inhibits vascular endothelial growth factor (VEGF), which is responsible for the excessive formation of blood vessels in the retina.

The MHRA approval is based on a totality of evidence including analytical, clinical and manufacturing data. In a randomized, double-masked, parallel group, multicentred phase III study, the efficacy, safety, pharmacokinetics and immunogenicity of ONGAVIA® was proven comparable to the reference drug Lucentis® (ranibizumab) in patients with age-related neovascular (wet) macular degeneration (nAMD).

The commercial launch of ONGAVIA® in the UK by Teva Pharmaceutical Industries Ltd., which has licensed the distribution rights from Bioeq AG under an exclusive strategic partnership, is expected to follow as soon as possible and targets to be the first available Biosimilar for Lucentis® in Europe.

<sup>1</sup>Lucentis® is a registered trademark of Genentech Inc.

**About Bioeq AG:**

Bioeq is a Swiss biopharmaceutical joint venture between the Polpharma Biologics Group B.V. and Formycon AG. Bioeq develops, licenses and commercialises biosimilars.

[www.bioeq.ch](http://www.bioeq.ch)

**About Teva:**

Teva Pharmaceutical Industries Ltd. (NYSE and TASE: TEVA) has been developing and producing medicines to improve people’s lives for more than a century. We are a global leader in generic, biosimilar and specialty medicines with a portfolio consisting of over 3,500 products in nearly every therapeutic area. Around 200 million people around the world take a Teva medicine every day and are served by one of the largest and most complex supply chains in the pharmaceutical industry. Along with our established presence in generics, we have significant innovative research and operations supporting our growing portfolio of specialty and biopharmaceutical products. Learn more at

[www.tevapharm.com](http://www.tevapharm.com).

**About Biosimilars:**

Since their introduction in the 1980s, biopharmaceuticals have revolutionised the treatment of serious diseases such as cancer, diabetes, rheumatoid arthritis, multiple sclerosis and eye diseases. In the coming years, many of these biotech drugs will lose their patent protection. Biosimilars are follow-on versions of biopharmaceuticals, for which exclusivity has expired. They are approved via stringent

regulatory pathways in highly regulated markets (such as EU, US, UK, Japan, Canada, Australia) based on proven similarity of the biosimilar with the originator biopharmaceutical reference product.

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