Press Release, August 29, 2022

European Commission approves FYB201/Ranivisio®[1] (Ranivisio - Ranibizumab), a biosimilar to Lucentis®[2]

Zug, Munich, Amsterdam – Bioeq AG ("Bioeq"), Formycon AG ("Formycon") and Polpharma Biologics Group BV ("Polpharma Biologics") jointly announce that the European Commission ("EC") has granted marketing authorization ("MA") for Ranivisio® (Ranivisio – Ranibizumab), a biosimilar to Lucentis® (ranibizumab-injection), for the treatment for several serious retinal diseases in the European Union ("EU").[i]

EC approval follows a positive opinion issued in June 2022 by the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) and is applicable to all 27 European Union member states plus Iceland, Norway and Liechtenstein.

Ranivisio® is indicated for the treatment of neovascular (wet) age-related macular degeneration (nAMD), the treatment of visual impairment due to diabetic macular oedema (DME) or choroidal neovascularization (CNV), the treatment of proliferative diabetic retinopathy (PDR), as well as the treatment of visual impairment due to macular oedema secondary to retinal vein occlusion (branch RVO or central RVO).[i]

Ranivisio® was developed by Bioeq, a Joint Venture between Formycon and Polpharma Biologics. Mid 2021, Teva Pharmaceutical Industries Ltd. ("Teva") entered into a strategic partnership for the exclusive commercialization of the product in Europe and selected other countries. Commercial launches across Europe are planned over the coming year, and the treatment is already available in the UK under the tradename Ongavia®[3], following its approval by the Medicines and Healthcare products Regulatory Agency (MHRA) in May 2022.

The EU-approval is based on the totality of evidence including analytical, nonclinical, clinical and manufacturing data. In a randomized, double-masked, parallel group, multicenter phase III study (COLUMBUS-AMD) it was shown that Ranivisio® is highly similar to the reference product Lucentis® in terms of comparable efficacy, safety, pharmacokinetics and immunogenicity in patients with age-related neovascular (wet) macular degeneration. [i]

AMD is caused by excessive growth of blood vessels in the retina. Ranibizumab inhibits vascular endothelial growth factor (VEGF), which is responsible for the excessive formation of these blood vessels in the retina. In developed countries AMD is the most common cause of severe visual impairment or blindness and it is estimated that up to 77 million Europeans will be affected by 2050.[ii] The consequences of AMD carry a significant burden for healthcare systems and societies as the increasing incidence of the condition is expected to absorb considerable amounts of healthcare resources and funds across the EU.

[1)] *Ranivisio® is a registered trademark of Bioeq AG.*
[2)] *Lucentis® is a registered trademark of Genentech Inc.*
[3)] *Ongavia® is a registered trademark of Teva Pharmaceutical Industries Ltd.*

About Bioeq:
Bioeq is a Swiss biopharmaceutical joint venture between the Polpharma Biologics Group and Formycon AG. Bioeq develops, licenses and commercializes biosimilars. www.bioeq.ch

About Formycon:
Formycon is a leading, independent developer of high-quality biopharmaceutical medicines, especially biosimilars. The company focuses on treatments in ophthalmology, immunology and on other key chronic diseases, covering the entire value chain from technical development to the clinical phase III as well as the preparation of dossiers for marketing approval. With its biosimilars, Formycon is making a major contribution towards providing as many patients as possible with access to vital and affordable medicines. Formycon currently has six biosimilars in development. Based on its extensive experience in the development of biopharmaceutical drugs, the company is also working on the development of a COVID-19 drug FYB207. www.formycon.com

About Polpharma Biologics:
Polpharma Biologics is an international biotechnology company with integrated operations in the European Union (EU), developing and manufacturing biosimilar medicines. Polpharma Biologics develops biosimilar products to treat a range of conditions in major therapeutic areas. Programs at Polpharma Biologics start in cell line development and transition through technical and clinical development to commercial-scale production, preparing drugs for future commercial partnerships with global pharmaceutical organizations. The company pipeline contains more than six biosimilars in different stages of development, including PB006 (biosimilar natalizumab) recently accepted for review by the EMA and FDA. www.polpharmabiologics.com

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.

About Biosimilars:
Since their introduction in the 1980s, biopharmaceuticals have revolutionized 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 – and by 2020, medications with revenues of approximately USD 100 billion will be off patent. 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, Japan, Canada, Australia) based on proven similarity of the biosimilar with the originator biopharmaceutical reference product. Global sales of biosimilars are estimated to exceed $15 billion by 2020. By 2030, analysts estimate that this figure could rise to over $60 billion.

Contact:
Dr. Thiemo Schreiber
VP Commercial & Operations, Bioeq AG
thiemo.schreiber@bioeq.ch
www.bioeq.ch

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References

[i] Ranivisio® (ranibizumab-xxxx). EU Summary of Product Characteristics, August 2021. Available at: https://www.ema.europa.eu/en. Last accessed August 2022.

[ii] Li JQ, Welchowski T, Schmid M, et al. Prevalence and incidence of age-related macular degeneration in Europe: a systematic review and meta-analysis British Journal of Ophthalmology 2020;104:1077-1084. Available at: https://bjo.bmj.com/content/104/8/1077. Last accessed August 2022.