Press Release // August 03. 2022

U.S. Food and Drug Administration (FDA) approves CIMERLI™* (ranibizumab-eqrn), the first and only biosimilar interchangeable with Lucentis®**

- CIMERLI™ is the only biosimilar approved for all five Lucentis® indications
- Commercially available in 0.3 mg and 0.5 mg dosages
- U.S. commercial launch by Coherus BioSciences, Inc. expected in early October 2022

Zug, Amsterdam, Munich – Bioeq AG ("Bioeq"), Polpharma Biologics Group BV ("Polpharma Biologics") and Formycon AG ("Formycon"), jointly announce that the U.S. Food and Drug Administration ("FDA") has approved CIMERLI™ (ranibizumab-eqrn), a biosimilar product exclusively interchangeable with Lucentis® (ranibizumab injection).

FYB201, was developed by Bioeq, a Joint Venture between Polpharma Biologics and Formycon. End of the year 2019, Coherus BioSciences, Inc. ("Coherus") entered into a license agreement for the exclusive commercialization of FYB201 under the brand name CIMERLI™ in the United States of America ("U.S.").

CIMERLI™ obtained approval from the FDA for the treatment of Age-Related Neovascular (wet) Macular Degeneration (nAMD) and other serious retinal diseases such as Diabetic Macular Edema (DME), Diabetic Retinopathy (DR), Macular Edema following Retinal Vein Occlusion (RVO) and Myopic Choroidal Neovascularization (mCNV). CIMERLI™ is the first and only interchangeable biosimilar with an exclusivity for 12 months after market launch that is indicated for the treatment of all five Lucentis® indications and, as such, is a new medical option for patients with serious retinal diseases.[1]

FDA-approval and interchangeability designation are based on a totality of evidence including analytical, nonclinical, clinical and manufacturing data. The efficacy, safety, pharmacokinetics and immunogenicity of CIMERLI™ were found to be comparable to the reference drug Lucentis® in patients with Age-Related Neovascular (wet) Macular Degeneration (nAMD). Clinical readouts from the randomized, double-masked, parallel group, multicenter phase III study (COLUMBUS AMD) have been published in the peer-reviewed journal, *Ophthalmology*.[2]

CIMERLI™ belongs to the anti-VEGF therapy class of biologics that have been revolutionary in helping retinal patients in maintaining or regaining vision. It inhibits vascular endothelial growth factor (VEGF), which is responsible for the excessive formation of blood vessels in the retina. The commercial launch of CIMERLI™ in the U.S by Coherus, is planned for early October in both 0.3mg and 0.5mg doses.

AMD is the leading cause of vision loss in adults aged over 60 years old in the U.S., and advanced age-related AMD is the world's leading cause of irreversible blindness.[3] As many as 11 million people in the U.S are living with a form of age-related AMD, a number which is expected to double to nearly 22 million by 2050.[3] Due to a projected increase in the incidence of diabetes across the U.S. over the next two decades, the burden of diabetic-related eye diseases, like DME and DR, are also likely to rise.[4] As the prevalence of serious retinal diseases increases, so do the costs of treating these diseases. The estimated global cost of visual impairment from AMD is more than $300 billion, including more than $250 billion in direct health care costs.[3]

* *CIMERLI™ is a trademark of Coherus BioSciences, Inc.*

** *Lucentis® is a registered trademark of Genentech Inc.*

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

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 European Medicines Agency (EMA) and FDA.

About Formycon:
Formycon (ISIN: DE000A1EWVY8 / WKN: A1EWVY) 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 four 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.

About Coherus BioSciences:
Coherus is a commercial stage biopharmaceutical company building a leading immuno-oncology franchise funded with cash generated by its commercial biosimilar business. In 2021, Coherus in-licensed toripalimab, an anti-PD-1 antibody, in the United States (U.S.) and Canada. A biologics license application for toripalimab for the treatment of nasopharyngeal carcinoma is under review by the FDA with a target action date of December 23, 2022. Coherus markets UDENYCA® (pegfilgrastim-cbqv), a biosimilar of Neulasta® in the U.S., and expects to launch CIMERLI™ (ranibizumab-eqrn) in the U.S. in early in October 2022, as well as the FDA-approved Humira® biosimilar YUSIMRY™ (adalimumab-aqvh) in the U.S. in 2023.

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, U.S., 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.

Disclaimer

This press release may contain forward-looking statements and information which are based on our current expectations and certain assumptions. Various known and unknown risks, uncertainties and other factors could lead to material differences between the actual future results, financial situation,

performance of the company, development of the products and the estimates given here. Such known and unknown risks and uncertainties comprise, among others, the research and development, the regulatory approval process, the timing of the actions of regulatory bodies and other governmental authorities, clinical results, changes in laws and regulations, product quality, patient safety, patent litigation, contractual risks and dependencies from third parties. With respect to pipeline products, Bioeq AG does not provide any representation, warranties or any other guarantees that the products will receive the necessary regulatory approvals or that they will prove to be commercially exploitable and/or successful. Bioeq AG assumes no obligation to update these forward-looking statements or to correct them in case of developments which differ from those anticipated. This document neither constitutes an offer to sell nor a solicitation of an offer to buy or subscribe for securities of Bioeq AG. No public offering of securities of Bioeq AG will be made nor is a public offering intended. This document and the information contained therein may not be distributed in or into the United States of America, Canada, Australia, Japan or any other jurisdictions, in which such offer or such solicitation would be prohibited. This document does not constitute an offer for the sale of securities in the United States.

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