Samsung Bioepis and Biogen Receive European Commission (EC) Approval for Aflibercept Biosimilar, OPUVIZ™

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- OPUVIZ™ is one of the first wave aflibercept biosimilars in Europe
- OPUVIZ is the second European Commission (EC)-approved ophthalmology biosimilar under Samsung Bioepis and Biogen's partnership
- EC approval based on robust totality of evidence confirming biosimilarity to reference aflibercept in terms of quality, efficacy, and safety

INCHEON, Korea and CAMBRIDGE, Mass. – November 18, 2024 – Samsung Bioepis Co., Ltd. and Biogen Inc. (Nasdaq: BIIB) today announced that the European Commission (EC) has approved OPUVIZ™ 40 mg/mL solution for injection in a vial, a biosimilar referencing Eylea[1,2] (aflibercept), developed and registered by Samsung Bioepis.

OPUVIZ, also known as SB15, is approved in adult patients for the treatment of neovascular (wet) age related macular degeneration (AMD), visual impairment due to macular oedema secondary to retinal vein occlusion (RVO; branch or central RVO), visual impairment due to diabetic macular oedema (DME), and visual impairment due to myopic choroidal neovascularisation (myopic CNV).

"Retinal disorders are affecting millions of people's lives in Europe, yet many patients face barriers to treatment due to high costs," said Byoungin Jung, Vice President, Regulatory Affairs at Samsung Bioepis. "The EC approval for OPUVIZ represents a major step toward our goal of expanding access to vital biologic therapies for those in need. We will continue working to expand access to our quality-assured, safe and effective biosimilars to improve patient's quality of life and support sustainability of healthcare systems."

"This approval is an exciting milestone for both patients and healthcare systems in Europe. OPUVIZ has the potential to create a new treatment option for eligible patients, while also easing the burden of costs associated with these retinal conditions," said Wolfram Schmidt, Head of Europe at Biogen. "We are delighted to continue our partnership with Samsung Bioepis, with the approval of our fifth biosimilar treatment option in Europe."

The EC approval was based on a totality of evidence including analytical, non-clinical data, and clinical data. A randomized, double-masked, parallel group, multicenter Phase 3 study demonstrated equivalent efficacy and comparable safety, immunogenicity, and pharmacokinetics (PK) profiles between SB15 and reference aflibercept (AFL). The primary endpoint was met in terms of change from baseline in best corrected visual acuity (BCVA) at week 8, and the 32-week interim analysis and 56-week analysis demonstrated comparability in other secondary efficacy, safety, immunogenicity, and PK endpoints between SB15 and AFL.[3, 4]

OPUVIZ is the second ophthalmology biosimilar approved in Europe and fifth biosimilar in the portfolio developed by Samsung Bioepis with commercialization rights held by Biogen, which includes BYOOVIZ™ (ranibizumab), BENEPALI™ (etanercept), IMRALDI™ (adalimumab) an FLIXABI™ (infliximab). In November 2019, Samsung Bioepis and Biogen announced that they had entered into a commercialization agreement for two ophthalmology biosimilar candidates, BYOOVIZ (SB11, ranibizumab) and OPUVIZ (SB15, aflibercept), in the U.S., Canada, Europe and certain other markets.

About the SB15 Phase 3 study[3,4]

The study is a randomized, double-masked, parallel group phase 3 study conducted at 56 centers in 10 countries from June 2020 to March 2022, including follow-up through 56 weeks. Of 549 screened participants, 449 participants 50 years and older with treatment-naive nAMD were randomized 1:1 to receive either SB15 (n = 224) or AFL (n = 225). At Week 32, patients were re-randomized to either continue SB15 or AFL, or switch from AFL to SB15 resulting in three treatment groups; continuing SB15 (SB15/SB15, n=219), continuing AFL (AFL/AFL, n=108), switching from AFL to SB15 (AFL/SB15, n=111). In total, 425 patients completed up to Week 56. Key efficacy endpoints of the study were 1) change from baseline in best corrected visual acuity (BCVA), 2) change from baseline in central subfield thickness (CST), and 3) proportion of patients with intra or sub-retinal fluid.

About Samsung Bioepis Co., Ltd.

Established in 2012, Samsung Bioepis is a biopharmaceutical company committed to realizing healthcare that is accessible to everyone. Through innovations in product development and a firm commitment to quality, Samsung Bioepis aims to become the world's leading biopharmaceutical company. Samsung Bioepis continues to advance a broad pipeline of biosimilar candidates that cover a spectrum of therapeutic areas, including immunology, oncology, ophthalmology, hematology, nephrology, and endocrinology. For more information, please visit: www.samsungbioepis.com and follow us on social media – X, LinkedIn.

About Biogen

Founded in 1978, Biogen is a leading biotechnology company that pioneers innovative science to deliver new medicines to transform patients' lives and to create value for shareholders and our communities. We apply deep understanding of human biology and leverage different modalities to advance first-in-class treatments or therapies that deliver superior outcomes. Our approach is to take bold risks, balanced with return on investment to deliver long-term growth.

We routinely post information that may be important to investors on our website at www.biogen.com. Follow us on social media - Facebook, LinkedIn, X, YouTube.

Biogen Safe Harbor

This news release contains forward-looking statements, including but not limited to those relating to the

potential benefits, safety and efficacy of OPUVIZ; the timing and status of current and future regulatory filings; risks and uncertainties associated with drug development and commercialization, including OPUVIZ; the potential of Biogen's commercial business and pipeline programs, including BYOOVIZ, BENEPALI, IMRALDI, FLIXABI and OPUVIZ; the anticipated benefits and potential of Biogen's collaboration arrangements with Samsung Bioepis; and Biogen's strategy and plans. These forward-looking statements may be accompanied by words such as "aim," "anticipate," "believe," "could," "estimate," "expect," "forecast," "intend," "may," "plan," "potential," "possible," "will," "would" and other words and terms of similar meaning. Drug development and commercialization involve a high degree of risk, and only a small number of research and development programs result in commercialization of a product. Results in early stage clinical trials may not be indicative of full results or results from later stage or larger scale clinical trials and do not ensure regulatory approval. You should not place undue reliance on these statements.

These statements involve risks and uncertainties that could cause actual results to differ materially from those reflected in such statements, including without limitation, actual timing and content of submissions to and decisions made by the regulatory authorities regarding OPUVIZ; regulatory submissions may take longer or be more difficult to complete than expected; regulatory authorities may require additional information or further studies, or may fail or refuse to approve or may delay approval of OPUVIZ; risks of unexpected costs or delays or other unexpected hurdles; uncertainty of success in the development and potential commercialization of OPUVIZ, which may be impacted by, among other things, the level of preparedness of healthcare providers to treat patients, difficulties in obtaining or changes in the availability of reimbursement for OPUVIZ and other unexpected difficulties or hurdles; the occurrence of adverse safety events; unexpected concerns that may arise from additional data or analysis; failure to protect and enforce data, intellectual property and other proprietary rights and uncertainties relating to intellectual property claims and challenges; risks of legal actions, regulatory scrutiny or other challenges to biosimilars, results of operations and financial condition; product liability claims; and third party collaboration risks. The foregoing sets forth many, but not all, of the factors that could cause actual results to differ from Biogen's expectations in any forward-looking statement. Investors should consider this cautionary statement as well as the risk factors identified in Biogen's most recent annual or quarterly report and in other reports Biogen has filed with the U.S. Securities and Exchange Commission. These statements are based on Biogen's current beliefs and expectations and speak only as of the date of this news release. Biogen does not undertake any obligation to publicly update any forward-looking statements.

References:

1. Eylea is a trademark of Regeneron Pharmaceuticals
2. European Medicines Agency. Eylea Product Information. Available at https://www.ema.europa.eu/en/documents/product-information/eylea-epar-product-information_en.pdf [Accessed November 2024]
3. Woo SJ, Bradvica M, Vajas A, et al. Efficacy and Safety of the Aflibercept Biosimilar SB15 in Neovascular Age-Related Macular Degeneration: A Phase 3 Randomized Clinical Trial. *JAMA Ophthalmol*. 2023;141(7):668–676. doi:10.1001/jamaophthalmol.2023.2260
4. Sadda SR, Bradvica M, Vajas A, et al. Biosimilar SB15 versus reference aflibercept in neovascular age-related macular degeneration: 1-year and switching results of a phase 3 clinical trial. *BMJ Open Ophthalmol*. 2023;8(1):e001561. doi:10.1136/bmjophth-2023-001561

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