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Korea's Samsung Bioepis gains full rights to BYOOVIZ biosimilar from Biogen in Europe

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BYOOVIZ, approved by the European Commission (EC) in August 2021 as the first ophthalmology biosimilar in Europe

South Korea-based Samsung Bioepis has entered into an Asset Purchase Agreement (APA) with Biogen regarding Samsung Bioepis' two ophthalmology assets: BYOOVIZ (ranibizumab), a biosimilar referencing Lucentis (ranibizumab) and OPUVIZ™ (aflibercept), a biosimilar referencing Eylea (aflibercept) — in Europe.

Samsung Bioepis will have full responsibility for commercialization of BYOOVIZ upon the transfer of commercial rights from Biogen back to Samsung Bioepis, effective as of January 2026.

"We are pleased to announce our direct commercialisation initiative for BYOOVIZ in Europe. We will work closely with Biogen to ensure a seamless transition and the continued delivery of services to our customers and patients in Europe," said Linda Choi MacDonald, Executive Vice President and Global Head of Commercial, at Samsung Bioepis. "Samsung Bioepis will continue to broaden our reach to patients across Europe by reinforcing our leadership and expertise in biosimilars."

BYOOVIZ (ranibizumab) was approved by the European Commission (EC) in August 2021 as the first ophthalmology biosimilar in Europe for the treatment of patients with Neovascular (Wet) Age-Related Macular Degeneration (AMD), Macular Edema following Retinal Vein Occlusion (RVO), and Myopic Choroidal Neovascularization (mCNV). BYOOVIZ became commercially available in several countries within Europe from March 2023. OPUVIZ (aflibercept) was approved by the EC in November 2024 and by the Medicines and Healthcare products Regulatory Agency (MHRA) in April 2025 for the treatment of patients with Wet AMD, Visual Impairment due to Macular Oedema Secondary to RVO, Visual Impairment due to Diabetic Macular Edema (DME), and Visual Impairment due to mCNV. OPUVIZ will not be launched until after the lapse or revocation of relevant patent(s) for the reference biologic Eylea that also covers OPUVIZ in Europe.