

FDA Approves First Biosimilars to Eylea

Aflibercept-jbvf (Yesafili; Biocon Biologics) and aflibercept-yszy (Opuviz; Biogen) are the first interchangeable biosimilars to aflibercept (Eylea; Regeneron).

The FDA approved aflibercept-jbvf (Yesafili; Biocon Biologics) and aflibercept-yszy (Opuviz; Biogen), the first interchangeable biosimilars to aflibercept (Eylea; Regeneron). Aflibercept inhibits vascular endothelial growth factor, preventing abnormal blood vessel growth in the eye, thus slowing down or reducing damage to the retina to help preserve vision.

Yesafili and Opuviz can treat neovascular age-related macular degeneration, macular edema after retinal vein occlusion, diabetic macular edema, and diabetic retinopathy. Both drugs are administered intravitreally as a 2 mg injectable solution for patients.

The approval was based on a comprehensive review of scientific evidence that demonstrated each product was highly similar to the reference product and have no clinically meaningful differences to Eylea. The data compared each product to the reference product on an analytical level and in comparative clinical studies, according to a press release.

For the analytical comparison, multiple lots of each product were compared across a broad range of product qualities and the similarity for structural and functional features was confirmed, including safety and efficacy. There were no clinical meaningful differences found between either product to Eylea in efficacy, safety, and immunogenicity. This data supports the approval as interchangeable with Eylea.



Reference

FDA approves first interchangeable biosimilars to Eylea to treat macular degeneration and other eye conditions. News release. FDA. May 20, 2024. Accessed May 20, 2024. https://www.fda.gov/drugs/news-events-human-drugs/fda-approves-first-interchangeable-biosimilars-eylea-treat-macular-degeneration-and-other-eye?utm_medium=email&utm_source=govdelivery

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