Opuviz™ (aflibercept-yszy) and Yesafili™ (aflibercept-jbvf)– New first-time interchangeable biosimilar approvals

- On May 20, 2024, the FDA announced the approval of Samsung Bioepis/Biogen's Opuviz (aflibercept-yszy) and Biocon's Yesafili (aflibercept-jbvf), biosimilar and *interchangeable* to Regeneron's Eylea (aflibercept).
    - Opuviz and Yesafili are the first FDA-approved biosimilars to Eylea.
- Opuviz, Yesafili and Eylea share the following indications for the treatment of:
    - Neovascular (wet) age-related macular degeneration (AMD)
    - Macular edema following retinal vein occlusion (RVO)
    - Diabetic macular edema (DME)
    - Diabetic retinopathy (DR).
- In addition, Eylea is also approved for the treatment of retinopathy of prematurity (ROP).
- Eylea is also available as Eylea HD indicated for AMD, DME, and DR.
- The approvals of Opuviz and Yesafili are based on review of a comprehensive data package and totality of evidence demonstrating a high degree of similarity to its reference product, Eylea.
- Evidence also demonstrated that Opuviz and Yesafili met the other legal requirements to be *interchangeable* with Eylea at the pharmacy level.
- Opuviz and Yesafili are contraindicated in patients with ocular or periocular infections or active intraocular inflammation, and in patients with known hypersensitivity to aflibercept or any of the excipients in Opuviz or Yesafili.
- Warnings and precautions for Opuviz and Yesafili include endophthalmitis, retinal detachments, and retinal vasculitis with or without occlusion; increase in intraocular pressure; and thromboembolic events.
- The most common adverse reactions (≥ 5%) with Opuviz or Yesafili use were conjunctival hemorrhage, eye pain, cataract, vitreous detachment, vitreous floaters, and increased intraocular pressure.
- The recommended dosage of Opuviz or Yesafili for patients with AMD is 2 mg (0.05 mL of 40 mg/mL solution) administered by intravitreal injection every 4 weeks (approximately every 28 days, monthly) for the first 12 weeks (3 months), followed by 2 mg (0.05 mL of 40 mg/mL solution) via intravitreal injection once every 8 weeks (2 months).
- The recommended dosage of Opuviz or Yesafili for patients with RVO is 2 mg (0.05 mL of 40 mg/mL solution) administered by intravitreal injection once every 4 weeks (approximately every 25 days, monthly).
- The recommended dosage of Opuviz or Yesafili for patients with DME or DR is 2 mg (0.05 mL of 40 mg/mL solution) administered by intravitreal injection every 4 weeks (approximately every 28 days,

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monthly) for the first 5 injections, followed by 2 mg (0.05 mL of 40 mg/mL solution) via intravitreal injection once every 8 weeks (2 months).

- Refer to the Opuviz and Yesafili drug labels for additional dosing details.
- Refer to the Eylea drug label for dosing for ROP.
- Samsung Bioepis/Biogen's launch plans for Opuviz are pending. Biocon's launch plans for Yesafili are pending. Opuviz and Yesafili will be available as a 2 mg (0.05 mL of 40 mg/mL) solution in a single-dose vial.