Enzeevu™ (aflibercept-abzv) – New biosimilar approval

- On August 12, 2024, Sandoz announced the FDA approval of Enzeevu (aflibercept-abzv), biosimilar to Regeneron's Eylea® (aflibercept).
    - Enzeevu is the fourth biosimilar to Eylea. Samsung Bioepis/Biogen's Opuviz™ (aflibercept-yszy) and Biocon's Yesafili™ (aflibercept-jbvf) have previously been approved as biosimilar and *interchangeable* to Eylea. Formycon's Ahzantive™ (aflibercept-mrbb) has also been approved as biosimilar to Eylea.
    - The FDA "provisionally determined" that Enzeevu qualifies for *interchangeable* status. The first approved *interchangeable* biosimilars to Eylea have unexpired exclusivity remaining.
- Enzeevu, Ahzantive, Opuviz, Yesafili and Eylea share the indication of treatment of neovascular (wet) age-related macular degeneration (AMD).
- Ahzantive, Opuviz, Yesafili and Eylea share the following indications for the treatment of:
    - 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 approval of Enzeevu is based on review of a comprehensive data package and totality of evidence demonstrating a high degree of similarity to its reference product, Eylea.
- Enzeevu is 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 Enzeevu.
- Warnings and precautions for Enzeevu 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 Enzeevu use were conjunctival hemorrhage, eye pain, cataract, vitreous detachment, vitreous floaters, and increased intraocular pressure.
- The recommended dosage of Enzeevu 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).
    - Refer to the Enzeevu drug label for additional dosing details.
- Refer to the Eylea drug label for dosing for RVO, DME, DR and ROP.

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- Sandoz's launch plans for Enzeevu are pending. Enzeevu will be available as a 2 mg (0.05 mL of 40 mg/mL) solution in a single-dose vial and single-dose prefilled syringe.