Byooviz™ (ranibizumab-nuna) – New biosimilar approval

- On September 17, 2021, the FDA announced the approval of Samsung Bioepis and Biogen's Byooviz (ranibizumab-nuna), a biosimilar to Genentech's Lucentis (ranibizumab).
    - Byooviz is the first FDA-approved biosimilar to Lucentis.
    - The Byooviz approval is for the 10 mg/mL single-dose vial formulation. Lucentis is also available as a 6 mg/mL single-dose vial formulation and 6 mg/mL and 10 mg/mL single-use prefilled syringes.
- Byooviz and Lucentis share the following indications:
    - Neovascular (wet) age-related macular degeneration (AMD)
    - Macular edema following retinal vein occlusion (RVO)
    - Myopic choroidal neovascularization (mCNV)
- Lucentis is also approved for the treatment of diabetic macular edema and diabetic retinopathy.
- Byooviz has been approved as a biosimilar, ***not*** as an interchangeable product.
- The approval of Byooviz was based on a review of evidence that included extensive structural and functional characterization, comparative clinical efficacy and safety evaluations, including potential immunogenicity (type of immune response) that demonstrated Byooviz is biosimilar to Lucentis.
- Similar to Lucentis, Byooviz is contraindicated in patients with ocular or periocular infections and in patients with known hypersensitivity to ranibizumab products or any of the excipients in Byooviz.
- Warnings and precautions for Byooviz include endophthalmitis and retinal detachments, increases in intraocular pressure (IOP), and thromboembolic events.
- The most common adverse reactions with Byooviz use were conjunctival hemorrhage, eye pain, vitreous floaters, and increased IOP.
- For neovascular AMD, the recommended dose of Byooviz is 0.5 mg administered by intravitreal injection once a month (approximately 28 days).
    - Although not as effective, patients may be treated with 3 monthly doses followed by less frequent dosing with regular assessment. In the 9 months after three initial monthly doses, less frequent dosing with 4 to 5 doses on average is expected to maintain visual acuity while monthly dosing may be expected to result in an additional average 1 to 2 letter gain. Patients should be assessed regularly.
    - Although not as effective, patients may also be treated with one dose every 3 months after 4 monthly doses. Compared with continued monthly dosing, dosing every 3 months over the next 9 months will lead to an approximate 5-letter (1-line) loss of visual acuity benefit, on average. Patients should be assessed regularly.
- For macular edema following RVO, the recommended dose of Byooviz is 0.5 mg administered by intravitreal injection once a month (approximately 28 days).

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- For mCNV, the recommended initial dose of Byooviz is 0.5 mg administered by intravitreal injection once a month (approximately 28 days) for up to 3 months. Patients may be retreated if needed.

- Pursuant to a global license agreement with Genentech, Samsung Bioepis and Biogen will have freedom to market Byooviz as of June 2022. Byooviz will be available as a 10 mg/mL solution in a single-dose vial.