Susvimo™ (ranibizumab) – New drug approval

- On October 22, 2021, Genentech announced the FDA approval of Susvimo (ranibizumab), for the treatment of patients with neovascular (wet) age-related macular degeneration (AMD) who have previously responded to at least two intravitreal injections of a vascular endothelial growth factor (VEGF) inhibitor medication.

- Susvimo is a refillable implant surgically inserted into the eye during a one-time, outpatient procedure. Susvimo continuously delivers a customized formulation of ranibizumab over time. Ranibizumab is a VEGF inhibitor.

    - Ranibizumab is currently available under the brand name Lucentis® as an intravitreal injection (via prefilled syringes and vials) for treatment of neovascular (wet) AMD, macular edema following retinal vein occlusion, diabetic macular edema, diabetic retinopathy, and myopic choroidal neovascularization.

- The efficacy of Susvimo was established in a randomized, visual assessor-masked, active treatment-controlled study in 415 patients with AMD. Patients were randomized to receive continuous delivery of Susvimo via the Susvimo implant every 24 weeks or 0.5 mg intravitreal ranibizumab injections every 4 weeks. Each patient was required to have demonstrated a response to an anti-VEGF intravitreal agent prior to randomization. The primary endpoint was the change from baseline in distance best corrected visual acuity (BCVA) score averaged over week 36 and week 40.

    - Susvimo was equivalent to intravitreal ranibizumab injections. The adjusted mean change from baseline in BCVA score was 0.2 and 0.5, for Susvimo and ranibizumab injections, respectively (difference -0.3, 95% CI: -1.7, 1.1).

- Susvimo carries a boxed warning for endophthalmitis.

- Susvimo is contraindicated in patients with:

    - Ocular or periocular infections
    - Active intraocular inflammation
    - Hypersensitivity

- Additional warnings and precautions for Susvimo include rhegmatogenous retinal detachment; implant dislocation; vitreous hemorrhage; conjunctival erosion or retraction; conjunctival bleb; postoperative decrease in visual acuity; air bubbles causing improper filling of the implant; and deflection of implant.

- The most common adverse reactions with Susvimo use were conjunctival hemorrhage, conjunctival hyperemia, iritis, and eye pain.

- The recommended dose of Susvimo is 2 mg (0.02 mL of 100 mg/mL solution) continuously delivered via the Susvimo ocular implant with refills administered every 24 weeks (approximately 6 months).

    - Supplemental treatment with 0.5 mg (0.05 mL of 10 mg/mL) intravitreal ranibizumab injection may be administered in the affected eye while the Susvimo implant is in place and if clinically necessary.
    - Refer to the Susvimo drug label for complete dosing and administration recommendations.

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- Genentech plans to launch Susvimo in the coming months. Susvimo will be available as a 100 mg/mL solution in a single-dose vial.

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