Susvimo® (ranibizumab) – New indication

- On February 4, 2025, Genentech announced the FDA approval of Susvimo (ranibizumab), for the **treatment of patients with diabetic macular edema (DME) who have previously responded to at least two intravitreal injections of a vascular endothelial growth factor (VEGF) inhibitor medication**.

- Susvimo is also approved 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 VEGF inhibitor medication.

- The approval of Susvimo for the new indication was based on a randomized, visual assessor-masked, active treatment-controlled study in 634 patients with DME. Patients were randomized to receive continuous delivery of Susvimo via the implant every 24 weeks or 0.5 mg intravitreal ranibizumab injections every 4 weeks. The primary endpoint was the change from baseline in distance Best Corrected Visual Acuity (BCVA) score averaged over week 60 and week 64.

    - **Susvimo demonstrated that it was noninferior to intravitreal ranibizumab injections administered every 4 weeks**. The change in BCVA scores from baseline were 9.6 and 9.4 for Susvimo and intravitreal ranibizumab, respectively (difference 0.2, 95% CI: -1.2, 1.6).

- Susvimo carries a boxed warning for **endophthalmitis**.

- The recommended dose of Susvimo for both of its indications 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.