Susvimo® (ranibizumab) – New indication

- On May 21, 2025, Roche announced the FDA approval of Susvimo (ranibizumab), for the **treatment of patients with diabetic retinopathy (DR) 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 neovascular (wet) age-related macular degeneration and diabetic macular edema (DME).

- The approval of Susvimo for the new indication was based on a randomized, visual assessor and reading center-masked study in 174 patients with moderately-severe to severe non-proliferative DR without center-involved DME. Patients were randomized to continuous delivery of Susvimo via the implant every 36 weeks or to clinical observation. Prior to the implant procedure, two loading doses of intravitreal ranibizumab were administered in the study eye. The primary endpoint was the proportion of patients with a ≥ 2-step improvement on the Early Treatment Diabetic Retinopathy Study Diabetic Retinopathy Severity Scale (ETDRS-DRSS) from baseline at week 52.

    — The primary endpoint was met by 80% of patients in the Susvimo arm vs. 9% in the clinical observation arm (difference 71, 95% CI: 61, 81; $p < 0.01$).

- Susvimo carries a boxed warning for endophthalmitis.

- 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 36 weeks (approximately 9 months).

    — Refer to the Susvimo drug label for dosing for its other indications.