Eylea® (aflibercept) – Expanded indication

- On May 13, 2019, Regeneron announced the FDA approval of Eylea (aflibercept), for the treatment of patients with diabetic retinopathy (DR).
    - Previously, Eylea was indicated for the treatment of patients with DR in patients with diabetic macular edema (DME).
- Eylea is also approved for the treatment of patients with neovascular (wet) age-related macular degeneration, macular edema following retinal vein occlusion, and DME.
- The approval of the expanded indication for Eylea was based on the PANORAMA study enrolling 402 patients with moderately severe to severe nonproliferative DR, without central-involved DME. Patients received one of three treatments: 1) 3 initial monthly Eylea 2 mg injections followed by one injection after 8 weeks and then one injection every 16 weeks (2Q16); 2) 5 monthly Eylea 2 mg injections followed by one injection every 8 weeks (2Q8); and 3) sham treatment. The primary efficacy endpoint was the proportion of patients who improved by ≥ 2 steps on the Diabetic Retinopathy Severity Scale (DRSS) from baseline to week 24 in the combined Eylea groups and at week 52 in the 2Q16 and 2Q8 groups individually vs. sham.
    - At week 24, 58% of patients in the combined Eylea groups met the primary endpoint vs. 6% in the sham group (Adjusted difference: 52% [95% CI: 45, 60]).
    - At week 52, 65% of the 2Q16 Eylea-treated patients, 80% of the 2Q8 Eylea-treated patients vs. 15% of the sham treatment group met the primary endpoint (Adjusted difference for 2Q16 group: 50% [95% CI: 40, 60]; $p < 0.01$ and adjusted difference for 2Q8 group: 65% [95% CI: 56, 74]; $p < 0.01$).
- The recommended dose of Eylea for DR is 2 mg (0.05 mL) administered by intravitreal injection every 4 weeks (approximately every 28 days, monthly) for the first 5 injections, followed by 2 mg (0.05 mL) via intravitreal injection once every 8 weeks (2 months).
    - Although Eylea may be dosed as frequently as 2 mg every 4 weeks (approximately every 25 days, monthly), additional efficacy was not demonstrated in most patients when Eylea was dosed every 4 weeks compared to every 8 weeks. Some patients may need every 4 week (monthly) dosing after the first 20 weeks (5 months).
    - Eylea must only be administered by a qualified physician.
    - Consult the Eylea drug label for dosing recommendations for other indications.