## Eylea® (aflibercept) – New orphan indication

- On February 8, 2023, the FDA approved Regeneron's Eylea (aflibercept), for treatment of retinopathy of prematurity (ROP).

- Eylea is also approved for the treatment of:

  - Neovascular (wet) age-related macular degeneration
  - Macular edema following retinal vein occlusion
  - Diabetic macular edema
  - Diabetic retinopathy

- ROP is a rare eye disease that often impacts infants who are born before 31 weeks of pregnancy. In the U.S., between 1,100 to 1,500 infants annually develop ROP that is severe enough to require medical treatment.

- The approval of Eylea for the new indication was based on two studies (BUTTERFLEYE and FIREFLEYE/FIREFLEYE NEXT). BUTTERFLEYE was a 52-week study. FIREFLEYE included 24 weeks of treatment and follow-up. FIREFLEYE NEXT was an observational follow-up of FIREFLEYE through week 52. The studies were conducted in 233 pre-term infants with ROP and compared Eylea treatment and laser photocoagulation therapy (laser). The primary endpoint of each study was the proportion of patients with absence of active ROP and unfavorable structural outcomes (retinal detachment, macular dragging, macular fold, retrolental opacity) at week 52 of chronological age.

  - The proportion of patients without clinically significant reactivations of ROP who also did not develop unfavorable structural outcomes (78.7% to 79.6% with Eylea and 77.8% to 81.6% with laser) was higher in each arm of each study than would have been expected in infants who had not received treatment.
  - Neither trial demonstrated superiority of one arm compared to the other arm. Neither trial demonstrated inferiority of one arm compared to the other arm.

- The recommended dose of Eylea for the treatment of ROP is 0.4 mg (0.01 mL or 10 microliters) administered by intravitreal injection. Treatment is initiated with a single injection per eligible eye and may be given bilaterally on the same day. Injections may be repeated in each eye. The treatment interval between doses injected into the same eye should be at least 10 days.

- Refer to the Eylea drug label for dosing for all its other indications.