## Vabysmo® (faricimab-svoa) – New indication

- On October 26, 2023, Genentech announced the FDA approval of Vabysmo (faricimab-svoa), for the treatment of patients with macular edema following retinal vein occlusion (RVO).

- Vabysmo is also approved for the treatment of patients with neovascular (wet) age-related macular degeneration (nAMD) and diabetic macular edema (DME).

- The approval of Vabysmo for the new indication was based on two randomized, double-masked studies (BALATON – in patients with macular edema following branch retinal vein occlusion, and COMINO – in patients with macular edema following central retinal vein occlusion/hemiretinal vein occlusion). A total of 1,282 newly diagnosed, treatment-naive patients were enrolled in these studies. In both studies, patients were randomized to either Vabysmo or the control arm receiving Eylea® (aflibercept). The primary endpoint was the change from baseline in Best Corrected Visual Acuity (BCVA) at week 24, measured by the Early Treatment Diabetic Retinopathy Study (ETDRS) Letter Score.

    — In both studies, Vabysmo demonstrated non-inferiority to Eylea for the primary endpoint.

| | BALATON | | COMINO | |
|---|---|---|---|---|
| | Vabysmo | Eylea | Vabysmo | Eylea |
| Mean change in BCVA as measured by ETDRS letter score from baseline (95% CI) | 16.9 (15.7, 18.1) | 17.5 (16.3, 18.6) | 16.9 (15.4, 18.3) | 17.3 (15.9, 18.8) |
| Difference in least square mean (95% CI) | -0.6 (-2.2, 1.1) | -- | -0.4 (-2.5, 1.6) | -- |

- The recommended dose of Vabysmo for the treatment of RVO is 6 mg (0.05 mL of 120 mg/mL solution) administered by intravitreal injection every 4 weeks (approximately every 28 ± 7 days, monthly) for 6 months.

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