

Vabysmo® (faricimab-svoa) - New indication

- On October 26, 2023, <u>Genentech announced</u> the FDA approval of <u>Vabysmo (faricimab-svoa)</u>, 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)	
mean (95% CI)	(-∠.∠, 1.1)		(-Z.S, I.O)	

- 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.



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