Genentech
A Member of the Roche Group

IMPORTANT DRUG WARNING

November 2023

Subject: VABYSMO® (faricimab-svoa), New Warnings and Precautions: Retinal Vasculitis and/or Retinal Vascular Occlusion

Dear Health Care Provider:

The purpose of this letter is to inform you of the updated safety information for VABYSMO. VABYSMO is a vascular endothelial growth factor (VEGF) and angiopoietin-2 (Ang-2) inhibitor indicated for the treatment of patients with:

- Neovascular (Wet) Age-Related Macular Degeneration (nAMD)
- Diabetic Macular Edema (DME)
- Macular Edema Following Retinal Vein Occlusion (RVO)

Risk of Retinal Vasculitis and/or Retinal Vascular Occlusion

An update to the Warnings and Precautions and Adverse Reactions - Postmarketing Experience sections of the US Prescribing Information has been made following spontaneous post-marketing reports of retinal vasculitis with or without occlusion in patients treated with VABYSMO. Retinal vasculitis with or without occlusion is a serious event that can cause permanent vision loss.

As of the end of August 2023, with 1.5 million vials dosed globally, the estimated reporting rate of retinal vasculitis with occlusion is 0.06/10,000 injections (for retinal vasculitis with or without occlusion: 0.17/10,000 injections).

Please also refer to section 6.2 in the USPI:

The following adverse reactions have been identified during postapproval use of VABYSMO. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

Eye disorders: retinal vasculitis with or without retinal vascular occlusion.

The benefit-risk profile of VABYSMO for all its approved indications continues to be favorable.

Prescriber Action

- Counsel patients about the benefits and risks of VABYSMO, including the risk of retinal vasculitis with or without retinal vascular occlusion.
- Patients treated with VABYSMO should be instructed to report any changes in vision without delay to permit prompt and appropriate management [see Patient Counseling Information (17)]. If the eye becomes red, sensitive to light, painful, or develops a change in vision, advise the patient to seek immediate care from an ophthalmologist.
- VABYSMO should be discontinued in patients who develop these events.
- Prescribers should refer to the Warnings and Precautions Section 5.4 of the US Prescribing Information.

Reporting Adverse Events and Company Contact

Health Care Providers should report any adverse events or product complaints suspected to be associated with the use of VABYSMO to Genentech at 1-833-EYE-GENE. Alternatively, this information may be reported to FDA's MedWatch reporting system by phone (1-800-FDA-1088) or online (www.fda.gov/medwatch).

Should you have any questions about the information in this letter or the safe and effective use of VABYSMO, please contact us at 1-833-EYE-GENE. This letter is not intended as a complete description of the benefits and risks related to the use of VABYSMO. Please refer to the enclosed full prescribing information for additional information.

Sincerely,

Toby Patterson, MBBS
Senior Vice President
Head of U.S. Medical Affairs