Apellis

November 2023

IMPORTANT DRUG WARNING

SUBJECT: SYFOVRE® (pegcetacoplan injection), 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 SYFOVRE. SYFOVRE is a complement inhibitor indicated for the treatment of patients with geographic atrophy (GA) secondary to age-related macular degeneration (AMD).

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, rare post-marketing reports of retinal vasculitis with or without occlusion in patients treated with SYFOVRE. Retinal vasculitis with or without occlusion is a serious event that may in some cases result in severe vision loss. This update was pursued in collaboration with FDA and is consistent with previous communications[1].

The estimated rate of retinal vasculitis with or without occlusion continues to be approximately 0.01% per injection based on an estimated 120,000 injections through November 18th. Since launch through the end of November 2023, there have been a total of 12 confirmed events of retinal vasculitis and two suspected events.

Please refer to section 6.2 in the USPI:

The following adverse reactions have been identified during post-approval use of SYFOVRE. 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 SYFOVRE for treatment of GA continues to be favorable.

[1] SYFOVRE: Insights on Case Reports of Retinal Vasculitis and Removal of 19-Gauge Filter Needle, Retina Today, *October 2023*

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Prescriber Action

- Counsel patients about the benefits and risks of SYFOVRE, including the risk of retinal vasculitis with or without retinal vascular occlusion.
- Patients treated with SYFOVRE 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 if a patient develops any change in vision such as flashing lights, blurred vision or metamorphopsia, instruct the patient to seek immediate care from an ophthalmologist [see Warnings and Precautions (5.1, 5.2, 5.3)].
- SYFOVRE should be discontinued in patients who develop these events.
- Prescribers should refer to the Warnings and Precautions Section 5.2 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 SYFOVRE to Apellis at 1-833-866-3346 and or email to medinfo@apellis.com 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 for the safe and effective use of SYFOVRE, please contact our medical information department at 1-833-866-3346. This letter is not intended as a complete description of the benefits and risks related to the use of SYFOVRE. Please refer to the enclosed full prescribing information for additional information.

Sincerely,

Caroline Baumal, M.D
Chief Medical Officer
Apellis Pharmaceuticals