Choose SYFOVRE

SYFOVRE®
(pegcetacoplan injection)
15 mg / 0.1 mL

Broad & Heterogeneous Trial Population[1,2]*

- >1200 Patients[1†]
- Lesions with and without subfoveal involvement[2‡]
- Bilateral and unilateral GA[2]
- With and without history of or active CNV in the fellow eye[2]

Achieved Continuous Reductions

- SYFOVRE reduced mean lesion growth rate from baseline vs sham through Month 24[1§]
- In a combined analysis of OAKS and DERBY, SYFOVRE slowed GA progression with increasing effects over time[2‖]
- Efficacy demonstrated in both monthly and EOM dosing[1]

Established Safety Profile

- Demonstrated safety in two Phase 3 trials (OAKS and DERBY) with >1200 patients followed for 24 months[1]

Binds to C3 and C3b

- C3 is the central protein in the complement cascade[3]
- SYFOVRE helps to regulate complement overactivation[1,4,5]

Provides Flexible Dosing

- 15 mg (0.1 mL of 150 mg/mL solution) of intravitreal injection administered once every 25–60 days[1]

Real World Use

60,000
VIALS DISTRIBUTED[¶]

*Patients with history of or active CNV in the study eye or GA secondary to a condition other than AMD were excluded.[2]

†1258 patients randomized among SYFOVRE and sham treatment groups.[1,2]

‡Lesions without subfoveal involvement defined as distance >0 µm from the atrophy junction to the foveal center.[2]

§OAKS: 22% (3.11 vs 3.98); 18% (3.26 vs 3.98) (monthly; EOM, respectively); DERBY: 18% (3.28 vs 4.00); 17% (3.31 vs 4.00) (monthly; EOM, respectively). SE in trials (monthly, EOM, sham pooled): OAKS: 0.15, 0.13, 0.14; DERBY: 0.13, 0.13, 0.17.[1]

‖With monthly dosing, OAKS and DERBY combined reductions in lesion growth rate vs sham were 13%, 19%, 20%, and 30% in the first, second, third, and fourth 6-month intervals, respectively. With EOM dosing, reductions were 12%, 17%, 17%, and 24%. Combined piecewise linear analysis did not have a prespecified statistical procedure controlling for type 1 error.[2]

¶Figure includes trade and sample vials shipped as of 07/23.

INDICATION

SYFOVRE® (pegcetacoplan injection) is indicated for the treatment of geographic atrophy (GA) secondary to age-related macular degeneration (AMD).

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

- SYFOVRE is contraindicated in patients with ocular or periocular infections, and in patients with active intraocular inflammation

Please see additional Important Safety Information on back and accompanying full Prescribing Information for more information.

ApellisAssist® is a program designed to help your patients on their treatment journey.

Permanent J-code for SYFOVRE: J2781

The Centers for Medicare & Medicaid Services (CMS) have assigned a permanent J-code for SYFOVRE effective for dates of service **on and after October 1, 2023.**[6]

IMPORTANT SAFETY INFORMATION (CONT'D)

WARNINGS AND PRECAUTIONS

- **Endophthalmitis and Retinal Detachments**
  - Intravitreal injections, including those with SYFOVRE, may be associated with endophthalmitis and retinal detachments. Proper aseptic injection technique must always be used when administering SYFOVRE to minimize the risk of endophthalmitis. Patients should be instructed to report any symptoms suggestive of endophthalmitis or retinal detachment without delay and should be managed appropriately.
- **Neovascular AMD**
  - In clinical trials, use of SYFOVRE was associated with increased rates of neovascular (wet) AMD or choroidal neovascularization (12% when administered monthly, 7% when administered every other month and 3% in the control group) by Month 24. Patients receiving SYFOVRE should be monitored for signs of neovascular AMD. In case anti-Vascular Endothelial Growth Factor (anti-VEGF) is required, it should be given separately from SYFOVRE administration.
- **Intraocular Inflammation**
  - In clinical trials, use of SYFOVRE was associated with episodes of intraocular inflammation including: vitritis, vitreal cells, iridocyclitis, uveitis, anterior chamber cells, iritis, and anterior chamber flare. After inflammation resolves, patients may resume treatment with SYFOVRE.
- **Increased Intraocular Pressure**
  - Acute increase in IOP may occur within minutes of any intravitreal injection, including with SYFOVRE. Perfusion of the optic nerve head should be monitored following the injection and managed as needed.

ADVERSE REACTIONS

- Most common adverse reactions (incidence ≥5%) are ocular discomfort, neovascular age-related macular degeneration, vitreous floaters, conjunctival hemorrhage.

Please see accompanying full Prescribing Information for more information.

AMD=age-related macular degeneration; CNV=choroidal neovascularization; EOM=every other month; GA=geographic atrophy; SE=standard error.

Trial Design: SYFOVRE safety and efficacy were assessed in OAKS (N=637) and DERBY (N=621), multi-center, 24–month, Phase 3, randomized, double-masked trials. Patients with GA (atrophic nonexudative age-related macular degeneration), with or without subfoveal involvement, secondary to AMD were randomly assigned (2:2:1:1) to receive 15 mg/0.1 mL intravitreal SYFOVRE monthly, SYFOVRE EOM, sham monthly, or sham EOM for 24 months. Change from baseline in the total area of GA lesions in the study eye (mm^2) was measured by fundus autofluorescence (FAF).[1,2]

References: 1. SYFOVRE (pegcetacoplan injection) [package insert]. Waltham, MA: Apellis Pharmaceuticals, Inc.; 2023. **2.** Data on file. Apellis Pharmaceuticals, Inc. **3.** Yates JRW, Sepp T, Matharu BK, et al; Genetic Factors in AMD Study Group. Complement C3 variant and the risk of age-related macular degeneration. *N Engl J Med.* 2007;357(6):553–561. doi:10.1056/NEJMoa072618. **4.** van Lookeren Campagne M, LeCouter J, Yaspan BL, Ye W. Mechanisms of age-related macular degeneration and therapeutic opportunities. *J Pathol.* 2014;232(2):151–164. doi:10.1002/path.4266. **5.** Holz FG, Strauss EC, Schmitz-Valckenberg S, van Lookeren Campagne M. Geographic atrophy: clinical features and potential therapeutic approaches. *Ophthalmology.* 2014;121(5):1079–1091. doi:10.1016/j.ophtha.2013.11.023. **6.** CMS HCPCS Application Summaries and Coding Recommendations. Accessed 07/24/2023. https://www.cms.gov/files/document/2023-hcpcs-application-summary-quarter-2-2023-drugs-and-biologicals.pdf.

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