Medical Xpress

FDA approves first treatment for geographic atrophy

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Pegcetacoplan (SYFOVRE) has been approved by the U.S. Food and

Drug Administration as the first and only treatment for geographic atrophy (GA), an advanced form of age-related macular degeneration.

Pegcetacoplan is an injection approved for GA patients with or without subfoveal involvement and allows a flexible dosing regimen of every 25 to 60 days.

The approval of pegcetacoplan was based on positive results from the OAKS (637 participants) and DERBY (621 participants) phase 3 studies. The OAKS and DERBY studies showed that compared with placebo, pegcetacoplan reduced the rate of GA lesion growth and demonstrated increasing treatment effects over time. Both monthly and every-other-month pegcetacoplan cut the rate of GA lesion growth through 24 months (OAKS: 22 percent monthly and 18 percent every other month; DERBY: 18 percent monthly and 17 percent every other month). The most common adverse reactions (incidence of ≥5 percent) were ocular discomfort, neovascular age-related macular degeneration, vitreous floaters, and conjunctival hemorrhage.

"The approval of SYFOVRE is the most important event in retinal ophthalmology in more than a decade," lead investigator for the OAKS study, Eleonora Lad, M.D., Ph.D., of the Duke University Medical Center in Durham, North Carolina, said in a statement. "Until now, there have been no approved therapies to offer people living with GA as their vision relentlessly declined. With SYFOVRE, we finally have a safe and effective GA treatment for this devastating disease, with increasing effects over time."

Approval of pegcetacoplan was granted to Apellis Pharmaceuticals.

More information: Press Release