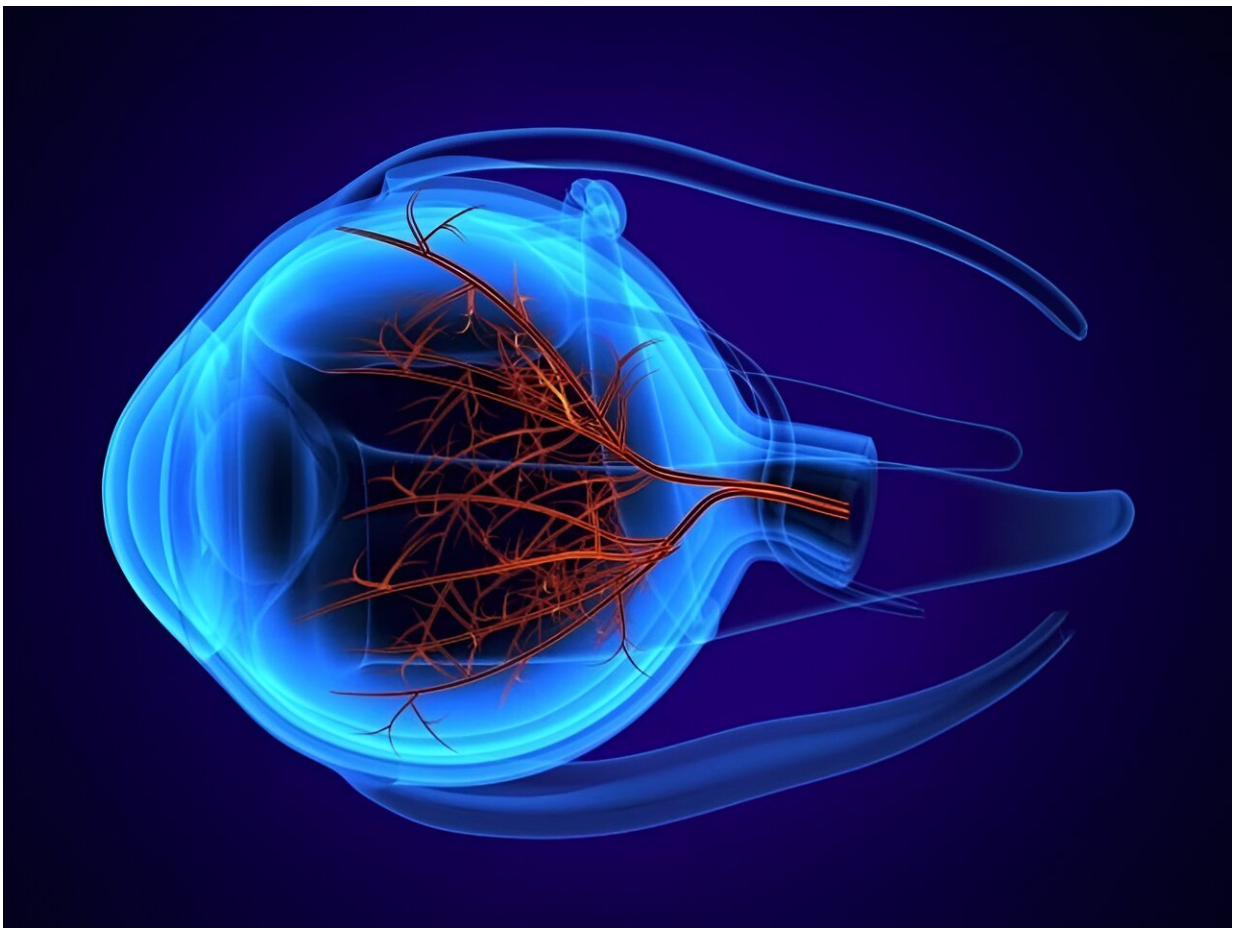
FDA approves Izervay for geographic atrophy tied to age-related macular degeneration

August 10 2023, by Lori Solomon



The U.S. Food and Drug Administration has approved Izervay (avacincaptad pegol intravitreal solution) for the treatment of geographic atrophy secondary to age-related macular degeneration.

The approval was based on two phase 3 clinical trials, in which patients received 2 mg intravitreal administration of Izervay. During a 12-month follow-up period, there was a statistically significant reduction in the rate of geographic atrophy growth in patients treated with Izervay versus sham. Slowing of disease progression was detected as early as six months, with up to a 35 percent reduction in the first year of treatment.

At 12 months, the most common adverse reactions (≥5 percent) seen in patients who received Izervay 2 mg were conjunctival hemorrhage (13 percent), increased intraocular pressure (9 percent), and blurred vision (8 percent).

"Geographic atrophy has a devastating impact on patients' lives and can lead to irreversible vision loss," Arshad M. Khanani, M.D., from Sierra Eye Associates in Reno, Nevada, said in a statement. "As a C5 inhibitor, Izervay has shown to slow geographic atrophy progression by targeting the source of retinal cell death and may preserve the upstream benefits of the complement system. The FDA approval of Izervay is great news for the retina community and our patients suffering from geographic atrophy."

Approval of Izervay was granted to Iveric Bio, an Astellas Pharma company.

More information: More Information