

Press Release

Iveric Bio Receives U.S. FDA Approval for IZERVAY™ (avacincaptad pegol intravitreal solution), a New Treatment for Geographic Atrophy

IZERVAY is the only approved GA treatment with a statistically significant reduction in the rate of GA progression at the 12-month primary endpoint across two Phase 3 clinical trials

IZERVAY slowed loss of photoreceptors and disease progression as early as six months

GA impacts an estimated 1.5 million people in the U.S. and can cause irreversible vision loss

TOKYO, August 7, 2023 – Astellas Pharma Inc. (TSE: 4503, President and CEO: Naoki Okamura, “Astellas”), today announced the U.S. Food and Drug Administration (FDA) approved IZERVAY™ (avacincaptad pegol intravitreal solution) for the treatment of geographic atrophy (GA) secondary to age-related macular degeneration (AMD) on August 4, 2023. IZERVAY, a new complement C5 inhibitor, is the only approved GA treatment with a statistically significant reduction ($p < 0.01$) in the rate of GA progression at the 12-month primary endpoint across two Phase 3 clinical trials.

Pravin U. Dugel, MD, President, Iveric Bio, An Astellas Company

“We are thrilled to receive FDA approval of IZERVAY and to offer a new therapy to physicians and appropriate patients in the U.S. Time matters, vision matters, and safety matters in this devastating progressive disease. We would like to thank everyone involved in reaching this milestone and helping us deliver on our commitment to pioneer transformational therapies for retinal diseases.”

The FDA approval was based on the GATHER1 and GATHER2 Phase 3 clinical trials, which evaluated the safety and efficacy of monthly 2 mg intravitreal administration of IZERVAY in patients with GA secondary to AMD. The rate of GA growth was evaluated at baseline, 6 months, and 12 months. In each registrational trial, over a 12-month period, the primary analysis showed a statistically significant reduction in the rate of GA growth in patients treated with IZERVAY compared to sham. Slowing of disease progression was observed as early as 6 months with up to a 35% reduction in the first year of treatment.

Arshad M. Khanani, MD, MA, FASRS, Director of Clinical Research at Sierra Eye Associates, Reno, Nevada

“Geographic atrophy has a devastating impact on patients’ lives and can lead to irreversible vision loss. As a C5 inhibitor, IZERVAY has shown to slow GA 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 GA.”

GA impacts an estimated 1.5 million people in the U.S.¹ However, approximately 75% of people living with GA in the U.S. are believed to be undiagnosed.² Without timely treatment, an estimated 66% of people with GA may become blind or severely visually impaired.³

Jason Menzo, Chief Executive Officer, Foundation Fighting Blindness

“Geographic atrophy can severely limit people’s ability to drive, read, and see the faces of their family and friends. This new treatment offers our patient community an important therapeutic option to potentially extend their ability to maintain independence.”

Across the GATHER clinical trial program, the most common adverse reactions ($\geq 5\%$) reported at 12 months in patients who received IZERVAY 2 mg were conjunctival hemorrhage (bleeding beneath the clear lining of the eye: 13%), intraocular pressure (increased fluid pressure of the eye: 9%) and blurred vision (8%).

IZERVAY is anticipated to be available in the U.S. in 2-4 weeks.

Astellas is reviewing potential financial impacts of this approval for the fiscal year ending March 31, 2024.

About IZERVAY™ (avacincaptad pegol intravitreal solution)

U.S. INDICATION

IZERVAY (avacincaptad pegol intravitreal solution) is indicated for the treatment of geographic atrophy (GA) secondary to age-related macular degeneration (AMD)

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

- IZERVAY is contraindicated in patients with ocular or periocular infections and in patients with active intraocular inflammation.

WARNINGS AND PRECAUTIONS

- Endophthalmitis and Retinal Detachments
 - Intravitreal injections, including those with IZERVAY, may be associated with endophthalmitis and retinal detachments. Proper aseptic injection technique must always be used when administering IZERVAY in order 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 IZERVAY was associated with increased rates of neovascular (wet) AMD or choroidal neovascularization (7% when administered monthly and 4% in the sham group) by Month 12. Patients receiving IZERVAY should be monitored for signs of neovascular AMD.
- Increase in Intraocular Pressure
 - Transient increases in intraocular pressure (IOP) may occur after any intravitreal injection, including with IZERVAY. Perfusion of the optic nerve head should be monitored following the injection and managed appropriately.

ADVERSE REACTIONS

- Most common adverse reactions (incidence $\geq 5\%$) reported in patients receiving IZERVAY were conjunctival hemorrhage, increased IOP, blurred vision, and neovascular age-related macular degeneration.

Please see full [Prescribing Information](#) for more information.

About Geographic Atrophy

Age-related macular degeneration (AMD) is the major cause of moderate and severe loss of central vision in aging adults, affecting both eyes in the majority of patients. The macula is a small area in the central portion of the retina responsible for central vision. As AMD progresses, the loss of retinal cells and the underlying blood vessels in the macula results in marked thinning and/or atrophy of retinal tissue. Geographic atrophy, associated with AMD, leads to further irreversible loss of vision in these patients.

About the GATHER Clinical Trials

IZERVAY met its primary endpoint in the GATHER1 ([NCT02686658](#)) clinical trial and the GATHER2 ([NCT04435366](#)) clinical trial, both of which were randomized, double-masked, sham-controlled, multicenter Phase 3 clinical trials. These trials evaluated the safety and efficacy of monthly 2 mg intravitreal administration of IZERVAY in patients with GA secondary to AMD. For the first 12 months in both trials, patients were randomized to receive either IZERVAY 2 mg or sham monthly. There were 286 participants enrolled in GATHER1 and 448 participants enrolled in GATHER2. The primary efficacy endpoints in both pivotal studies were based on GA area measured by fundus autofluorescence at three time points: baseline, month 6, and month 12. Safety was evaluated in over 700 patients with GA across the two trials.

About Astellas

Astellas Pharma Inc. is a pharmaceutical company conducting business in more than 70 countries around the world. We are promoting the Focus Area Approach that is designed to identify opportunities for the continuous creation of new drugs to address diseases with high unmet medical needs by focusing on Biology and Modality. Furthermore, we are also looking beyond our foundational Rx focus to create Rx+[®] healthcare solutions that combine our expertise and knowledge with cutting-edge technology in different fields of external partners. Through these efforts, Astellas stands on the forefront of healthcare change to turn innovative science into VALUE for patients. For more information, please visit our website at <https://www.astellas.com/en>.

About Iveric Bio

Iveric Bio, An Astellas Company, is a science-driven biopharmaceutical company focused on the discovery and development of novel treatments for retinal diseases with significant unmet medical needs. The Company is committed to having a positive impact on patients' lives by delivering high-quality, safe, and effective treatments designed to address debilitating retinal diseases including earlier stages of age-related macular degeneration. For more information on the Company, please visit www.ivericbio.com.

Cautionary Notes

In this press release, statements made with respect to current plans, estimates, strategies and beliefs and other statements that are not historical facts are forward-looking statements about the future performance of Astellas. These statements are based on management's current assumptions and beliefs in light of the information currently available to it and involve known and unknown risks and uncertainties. A number of factors could cause actual results to differ materially from those discussed in the forward-looking statements. Such factors include, but are not limited to: (i) changes in general economic conditions and in laws and regulations, relating to pharmaceutical markets, (ii) currency exchange rate fluctuations, (iii) delays in new product launches, (iv) the inability of Astellas to market existing and new products effectively, (v) the inability of Astellas to continue to effectively research and develop products accepted by customers in highly competitive markets, and (vi) infringements of Astellas' intellectual property rights by third parties.

Information about pharmaceutical products (including products currently in development) which is included in this press release is not intended to constitute an advertisement or medical advice.

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Contacts for inquiries or additional information:

Iveric Bio, An Astellas Company
Jeannie Neufeld
+1-973-219-9286
jeannie.neufeld@ivericbio.com

Astellas Pharma Inc. Corporate Communications
+81-3-3244-3201

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2. Data on file. Iveric Bio, Parsippany, NJ.
3. Colijn JM, et al. Enlargement of geographic atrophy from first diagnosis to end of life. *JAMA Ophthalmol*. 2021;139(7):743-750.