

Press Release

European Medicines Agency Accepts Iveric Bio's Marketing Authorization Application for Avacincaptad Pegol for Geographic Atrophy

TOKYO, August 18, 2023 – Astellas Pharma Inc. (TSE: 4503, President and CEO: Naoki Okamura, "Astellas"), today announced the European Medicines Agency (EMA) has accepted for regulatory review the marketing authorization application (MAA) for avacincaptad pegol (ACP), an investigational complement C5 inhibitor for the treatment of geographic atrophy (GA) secondary to age-related macular degeneration (AMD). The Committee for Medicinal Products for Human Use (CHMP) of the EMA will start its review of the MAA under the centralized licensing procedure for all 27 member states of the European Union (EU).

GA is a form of AMD that can cause irreversible vision loss.¹ Without timely treatment, an estimated 66% of people with GA may become blind or severely visually impaired.² Globally, approximately 5 million people are estimated to have GA at least in one eye.¹

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

"This acceptance of our EU Marketing Authorization Application is a key milestone in our global effort to help patients living with GA, a leading cause of blindness worldwide. We look forward to collaborating with CHMP throughout the review process and hope to make ACP available for patients in Europe."

The MAA is based on the GATHER1 and GATHER2 Phase 3 clinical trials, which evaluated the safety and efficacy of monthly 2 mg intravitreal administration of ACP in patients with GA secondary to AMD. 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 ACP compared to sham. Across the GATHER1 and GATHER2 clinical trials, safety was evaluated in over 700 patients with GA.

ACP was approved by the U.S. Food and Drug Administration as IZERVAY™ (avacincaptad pegol intravitreal solution) for the treatment of geographic atrophy (GA) secondary to age-related macular degeneration (AMD) on August 4, 2023.

This acceptance of the EU Marketing Authorization Application will have no impact on the financial forecasts of the current fiscal year ending March 31, 2024.

About Avacincaptad Pegol

Avacincaptad pegol (ACP) is an investigational drug for treatment of geographic atrophy (GA) secondary to age-related macular degeneration (AMD) that is currently under evaluation for safety and efficacy by the European Medicines Agency. ACP is approved in the U.S. as IZERVAY for the treatment of GA secondary to AMD. ACP is a complement C5 protein inhibitor. Overactivity of the complement system and the C5 protein are suspected to play a critical role in the development and growth of scarring and vision loss associated with GA secondary to AMD. By targeting C5, ACP has the potential to decrease activity of the complement system that causes the degeneration of retinal cells and potentially slow the progression of GA.

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

ACP 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 ACP in patients with GA secondary to AMD. For the first 12 months in both trials, patients were randomized to receive either ACP 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 trials.

About Astellas

Astellas Pharma Inc. is a pharmaceutical company conducting business in more than 70 countries around the world. Our Focus Area Approach 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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References

1. Boyer DS, et al. The pathophysiology of geographic atrophy secondary to age-related macular degeneration and the complement pathway as a therapeutic target. *Retina*. 2017;37(5):819-835.
2. Colijn JM, Liefers B, Joachim N, et al. Enlargement of geographic atrophy from first diagnosis to end of life. *JAMA Ophthalmol*. 2021;139(7):743-750.