Press Release

Astellas Provides Update on IZERVAY™ (avacincaptad pegol intravitreal solution) Supplemental New Drug Application

TOKYO, Nov.19, 2024 – Astellas Pharma Inc. (TSE: 4503, President and CEO: Naoki Okamura, "Astellas") today announced the U.S. Food and Drug Administration (FDA) issued a Complete Response Letter (CRL) on November 15, 2024, regarding the supplemental New Drug Application (sNDA) for IZERVAY™ (avacincaptad pegol intravitreal solution) for the treatment of geographic atrophy (GA) secondary to age-related macular degeneration (AMD). The sNDA sought to include positive two-year data in the U.S. Prescribing Information for IZERVAY based on results from the GATHER2 Phase 3 clinical trial, which evaluated the efficacy and safety of monthly (EM) and every other month (EOM) dosing through year 2.

The FDA stated the agency cannot approve the sNDA in its present form by the Prescription Drug User Fee Act (PDUFA) action date of November 19, 2024. The FDA comments outlined in the CRL are unrelated to the safety and benefit/risk of the use of IZERVAY; rather, the comments focus on a statistical matter related to labelling language proposed by Astellas.

Astellas is seeking further clarification from the FDA and looks forward to working with the agency to quickly address the agency's feedback.

Marci English, Senior Vice President, Biopharma and Ophthalmology Development, Astellas Pharma
"Astellas stands by the clinical profile of IZERVAY, the only FDA-approved GA treatment that consistently demonstrated statistically significant slowing of GA across two pivotal Phase 3 studies. While this is a disappointment for patients and physicians who rely on IZERVAY for the management of a chronic, progressive disease that can lead to irreversible vision loss, Astellas is unwavering in our commitment to the ophthalmology space and will continue to work with the FDA to advance solutions for those suffering from GA."

IZERVAY was approved by the U.S. FDAon August 4, 2023, for the treatment of GA secondary to AMD.

Astellas is reviewing potential financial impacts of this matter for the fiscal year ending March 31, 2025.

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 U.S. 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 ≥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.

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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