Press Release

U.S. FDA Accepts Astellas' Supplemental New Drug Application for IZERVAY™ (avacincaptad pegol intravitreal solution) for Geographic Atrophy

- sNDA seeks to include positive 2-year data for IZERVAY -
- Target action date set for November 19, 2024 -

TOKYO, April 1, 2024 – Astellas Pharma Inc. (TSE: 4503, President and CEO: Naoki Okamura, "Astellas") today announced it received notification from the U.S. Food and Drug Administration (FDA) of acceptance of the company's supplemental New Drug Application (sNDA) to include positive 2-year data in the U.S. Prescribing Information for IZERVAY™ (avacincaptad pegol intravitreal solution) for the treatment of geographic atrophy (GA) secondary to age-related macular degeneration (AMD). The sNDA is 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.

Under the Prescription Drug User Fee Act (PDUFA), the FDA has set a target action date of November 19, 2024. The acceptance follows the U.S. Centers for Medicare and Medicaid Services issuing a permanent J-code for IZERVAY, effective April 1, 2024, which is expected to accelerate patient access in the U.S.

Carolyn Sasse, Development Head, Cell and Gene Therapy, Astellas Pharma
"Astellas is committed to bringing innovative treatments to patients with retinal diseases including geographic atrophy. We are pleased with the FDA's decision to evaluate our application, and we look forward to working with the Agency throughout the review process."

The GATHER2 data demonstrated IZERVAY continued to reduce the rate of GA lesion growth in patients with GA secondary to AMD through 2 years versus sham. The treatment benefit with IZERVAY vs. sham was observed as early as 6 months, continued to increase over time through 2 years, and more than doubled over 2 years compared to year 1.

IZERVAY was well tolerated over 2 years in GATHER2, with one case of non-serious intraocular inflammation (IOI) and culture-positive endophthalmitis each, and zero cases of ischemic neuropathy or serious intraocular inflammation, including retinal vasculitis. Over 2 years, the incidence of choroidal neovascularization (CNV) was slightly increased between IZERVAY (11.6%) versus sham (9%).

Veeral S. Sheth, MD, MBA, FACS, FASRS, Partner and Director of Clinical Trials University Retina

“GA is a chronic, progressive disease that can lead to irreversible vision loss. Having IZERVAY approved for longer-term use based on the latest safety and efficacy data would be a welcome development for the retina community.”

IZERVAY was approved by the U.S. Food and Drug Administration on August 4, 2023, for the treatment of GA secondary to AMD and is currently under review by the European Medicines Agency.

Astellas has already reflected the impact from this result in its financial forecast for the fiscal year ending March 31, 2024.

About the GATHER2 Clinical Trial
GATHER2 (NCT04435366) was a randomized, double-masked, sham-controlled, multicenter Phase 3 clinical trial to evaluate the safety and efficacy of intravitreal administration of avacincaptad pegol (ACP) in 448 enrolled patients with GA secondary to AMD. ACP met its primary objective at 12 months, for which patients were randomized to receive either ACP or sham procedure monthly. In year 2 of the study, patients treated with ACP in year 1 were re-randomized to receive either ACP dosed monthly (EM, n=96) or every other month (EOM, n=93); patients who received sham in year 1 continued to receive sham in year 2 (n=203). IZERVAY is continuing to be evaluated in an open-label extension study.

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 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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