Press Release

U.S. FDA Approves Expanded Label for Astellas' IZERVAY™ (avacincaptad pegol intravitreal solution) for Geographic Atrophy

- IZERVAY dosing approved beyond 12 months -

TOKYO, February 13, 2025 – Astellas Pharma Inc. (TSE: 4503, President and CEO: Naoki Okamura, "Astellas") today announced the U.S. Food and Drug Administration (FDA) approved expanded U.S. Prescribing information for IZERVAY™ (avacincaptad pegol intravitreal solution) for the treatment of geographic atrophy (GA) secondary to age-related macular degeneration (AMD). As a result, IZERVAY is now approved without a limitation on duration of dosing—providing physicians and patients with greater flexibility when managing GA.

The approval follows Astellas' resubmission of the supplemental New Drug Application (sNDA) for IZERVAY on December 26, 2024, within days of meeting with the FDA to clarify the Agency's feedback provided in the Complete Response Letter (CRL) issued in November 2024.

Marci English, Senior Vice President, Biopharma and Ophthalmology Development, Astellas Pharma
"We are pleased with the FDA's decision to extend the use of IZERVAY for longer-term administration—further solidifying IZERVAY's status as a trusted choice for thousands of GA patients since its launch in 2023. To date, IZERVAY remains the only FDA-approved treatment to demonstrate a statistically significant slowing of GA across two pivotal studies."

The approved label update was based on positive results from the GATHER2 Phase 3 clinical trial, which evaluated the efficacy and safety of IZERVAY through year 2.

Since receiving a permanent J-code in April 2024, IZERVAY has had month-over-month growth in the U.S. with more than 210,000 vials distributed through the end of December 2024. Post-marketing safety reporting remains consistent with that observed in the clinical trial program, with no new or significant safety signals identified, providing confidence to prescribers in IZERVAY's safety profile.

Veeral S. Sheth, MD, MBA, FACS, FASRS, Partner and Director of Clinical Trials University Retina
"This is a welcome update for retina specialists, providing continued management options for treatment of this chronic, progressive disease that can lead to irreversible vision loss."

The GATHER2 study demonstrated that 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 versus 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 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 was slightly increased between IZERVAY (11.6%) versus sham (9%).

IZERVAY was approved by the U.S. Food and Drug Administration on August 4, 2023, for the treatment of GA secondary to AMD.

The impact of this matter on Astellas' financial results for the fiscal year ending March 31, 2025, is expected to be minor.

About IZERVAY™ (avacincaptad pegol intravitreal solution)

U.S. INDICATION AND IMPORTANT SAFETY INFORMATION

What is IZERVAY?
IZERVAY (avacincaptad pegol intravitreal solution) is a prescription eye injection, used to treat geographic atrophy (GA), the advanced form of dry age-related macular degeneration (AMD).

What is the most important information I should know about IZERVAY?
Do NOT receive IZERVAY if you:

- Have an infection in or around your eye
- Have active swelling in or around your eye that may include pain and redness

IZERVAY can cause serious side effects:

- Eye injections like the one for IZERVAY can cause an eye infection (endophthalmitis) or separation of layers of the retina (retinal detachment).
- Call your healthcare provider right away if you have redness of the eye, eye pain, increased discomfort, worsening eye redness, blurred or decreased vision, an increased number of small specks floating in your vision, flashes of light, or increased sensitivity to light.
- There is a risk of developing wet AMD with IZERVAY. You should report any symptoms (visual distortions such as straight lines seeming bent, deterioration in vision, dark spots, loss of central vision) to your healthcare provider to monitor.
- IZERVAY may cause a temporary increase in eye pressure after the injection. Your healthcare provider will monitor this after each injection.

Before receiving IZERVAY tell your healthcare provider about all of your medical conditions including if you:

- Have a history of seeing flashes of light or small specks floating in your vision and if you have a sudden increase of size and number of these specks.
- Have high pressure in the eye or if you have glaucoma.
- Are pregnant or breastfeeding, think you may be pregnant, or are planning to have a baby, ask your doctor for advice before taking this medicine.
- Are taking any medications, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Tell your healthcare provider about any medicine you take.

What should I avoid while receiving IZERVAY?

- Your vision may be impaired after receiving an eye injection or after an eye exam. Do not drive or use machinery until your vision has recovered sufficiently.

What are the most common side effects of IZERVAY?

- Blood in the white of the eye

- Increase in eye pressure
- Blurred vision
- Wet age-related macular degeneration

These are not all the possible side effects of IZERVAY. Tell your healthcare provider about any side effect that bothers you or that does not go away.

Call your healthcare provider for medical advice about side effects. You are encouraged to report negative side effects of prescription drugs to the FDA. Visit **www.fda.gov/medwatch** or call **1-800-FDA-1088**.

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 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 Astellas
Astellas is a global life sciences company committed to turning innovative science into VALUE for patients. We provide transformative therapies in disease areas that include oncology, ophthalmology, urology, immunology and women's health. Through our research and development programs, we are pioneering new healthcare solutions for diseases with high unmet medical need. Learn more at www.astellas.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.

###

Contacts for inquiries or additional information:

Beth Stevenson, US Therapeutic Area Communications
+1-910-200-4272
dorothy.stevenson@astellas.com

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