Press Release

Astellas to Present New Data in Geographic Atrophy at Upcoming Ophthalmology Annual Congresses

ARVO and RWC abstracts feature analyses on biomarkers, mechanism of disease, patient experience and other data from IZERVAY™ (avacincaptad pegol intravitreal solution) pivotal studies

TOKYO, May 1, 2025 – Astellas Pharma Inc. (TSE: 4503, President and CEO: Naoki Okamura, "Astellas"), maker of IZERVAY™ (avacincaptad pegol intravitreal solution), a C5 inhibitor for the treatment of geographic atrophy (GA)*, will highlight new data that enhances continued understanding of the science of GA, and the experience of patients living with the progressive disease at the Association for Research in Vision and Ophthalmology Annual Meeting (ARVO), May 4-8, Salt Lake City, Utah, and Retina World Congress (RWC), May 8-11, Fort Lauderdale, Florida.

The data comprises nine abstracts, including two oral presentations, featuring analyses on biomarkers, patient experience, mechanism of disease and other insights from the GATHER Phase 3 studies of IZERVAY for the treatment of GA secondary to age-related macular degeneration (AMD).

Marci English, Senior Vice President, Biopharma and Ophthalmology Development, Astellas Pharma
"Recognizing the early indicators and disease pathways of geographic atrophy are critical to helping patients preserve their existing vision for longer. We look forward to engaging with the retina community at ARVO and RWC to discuss the latest scientific insights in early diagnosis and effective management of GA."

Research highlights include:

- An oral presentation on the structure-function relationship between baseline central subfield ellipsoid zone (EZ) integrity and visual acuity at baseline and future vision loss
- An oral presentation on baseline EZ integrity features linked to GA progression in eyes with differential shifts in GA growth rate
- Multiple posters evaluating imaging data from the GATHER1 and GATHER2 studies, which link structure and function in GA
- Two preclinical posters with structural insights refining the mechanism of action, as well as pharmacokinetics and pharmacodynamics, of avacincaptad pegol (ACP)
- Data from qualitative studies assessing the experience of patients with GA in the U.S., Spain, Germany and France, including the impact of disease symptoms on health-related quality of life (HRQoL) and coping mechanisms used to manage symptoms of GA

Astellas Presentations at 2025 ARVO Annual Meeting

Presentation Title	Presenter	Presentation Details
Association of baseline central subfield ellipsoid zone integrity with baseline visual acuity and future vision loss in the GATHER clinical trials	R. Amine	**Type:** Oral **Presentation Number:** 4594 **Date:** May 7, 2025 3:30-3:45 PM MT
Understanding the experience of people living with geographic atrophy in the United States, Spain, France and Germany	N. Genova	**Type:** Poster **Posterboard Number:** 807 - B0259 **Date:** May 4, 2024 1:00-2:45 PM MT
Structural insights into the mechanism of inhabitation of C5 activation by avacincaptad pegol, an aptamer approved for the treatment of geographic atrophy secondary to age-related macular degermation	G. Musada	**Type:** Poster Presentation **Posterboard Number**: 2522 - B0235 **Date:** May 5, 2025 3:00 – 4:45 PM MT
Nonclinical pharmacology and pharmacokinetic properties of avacincaptad pegol, an aptamer against C5 approved for the treatment of geographic atrophy secondary to age-related macular degeneration	N. Lombardi	**Type:** Poster **Posterboard Number**: 2539 - B0252 **Date:** May 5, 2025 3:00 – 4:45 PM MT
iRORA phenotype characterization using fundus autofluorescence: GATHER2 post-hoc analysis for geographic atrophy secondary to AMD	G. Corradetti	**Type:** Poster **Posterboard Number**: 3468 - B0031 **Date:** May 6, 2025 1:15 – 3:00 PM MT
Association of ellipsoid zone integrity features with diffuse trickling fundus autofluorescence patterns in the GATHER1/GATHER2 clinical trials	L. Della Vecchia	**Type:** Poster **Posterboard Number**: 3512 - B0075 **Date:** May 6, 2025 1:15 – 3:00 PM MT
Structure-function link between ellipsoid zone integrity features and visual acuity in eyes with geographic atrophy in the GATHER1 and GATHER2 clinical trials	K. Matar	**Type:** Poster **Posterboard Number**: 4123 - A0121 **Date:** May 7, 2025 10:15 AM – 12:00 PM MT
Ellipsoid zone integrity features linked to differential shifts in geographic atrophy growth rate in the GATHER1 and GATHER2 clinical trials	A. Indurkar	**Type:** Poster **Posterboard Number**: 4220 - A0218 **Date:** May 7, 2025 10:15 AM – 12:00 PM MT

Astellas Presentations at RWC 2025 Meeting

Presentation Title	Presenter	Presentation Details
Ellipsoid zone integrity features linked to differential shifts in geographic atrophy growth rate in the GATHER1 and GATHER2 clinical trials	R. Downes	**Type:** Oral **Date:** May 9, 2025 2:38 – 2:43 pm ET

*avacincaptad pegol intravitreal solution (ACP) is approved for use as IZERVAY™ only in the U.S.

About IZERVAY™ (avacincaptad pegol intravitreal solution)

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 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.

In year 2 of the GATHER2 study, patients treated with IZERVAY in year 1 were re-randomized to receive either IZERVAY 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.

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