Press Release

Astellas Receives Conditional Approval for IZERVAY, making it the first and only approved treatment for the Suppression of Geographic Atrophy Growth in Japan

TOKYO, Sep 19, 2025 – Astellas Pharma Inc. (TSE: 4503, President and CEO: Naoki Okamura, "Astellas") today announced that the Japanese Ministry of Health, Labor and Welfare (MHLW) has granted Conditional Approval of IZERVAY (avacincaptad pegol intravitreal solution: ACP) for the suppression of geographic atrophy (GA) growth in atrophic age-related macular degeneration (AMD). This approval – achieved in just seven months through an expedited pathway designed to bring innovative treatments to patients with serious unmet need – makes ACP the first and only approved treatment for patients living with GA in Japan.

In the global GATHER1 and GATHER2 clinical trials, ACP met its primary endpoint by significantly reducing the rate of GA lesion growth compared with sham.[1,2] The mean rate of GA lesion growth reduction over 12 months was 35% in GATHER1 and 18% in GATHER2.[3] Sustained efficacy was observed over two years of follow-up, with efficacy observed as early as six months following the first injection.[1,2,4] ACP was consistently well tolerated across both the trials, with less than 2% of participants stopping treatment due to adverse events.[1,2]

Marci English, Senior Vice President, Biopharma and Ophthalmology Development, Astellas

"This approval highlights the strength of the GATHER clinical program and the value of continued innovation in ophthalmology. Under the Conditional Approval system, we will build on these findings with confirmatory studies to further strengthen the evidence base and expand understanding of how to best help people living with geographic atrophy."

GA is an advanced and irreversible form of age-related macular degeneration that causes progressive vision loss.[5] In Japan, GA is estimated to affect nearly 100,000 people.[6,7] Without timely treatment, an estimated 66% of people with GA become

legally blind or severely visually impaired – a devastating reality that destroys independence and wellbeing.[8,9]

ACP, a complement C5 inhibitor, significantly slowed the growth of GA lesions, which is expected to slow visual impairment by reducing activation of the complement system, which drives retinal cell degeneration.[3,10]

Astellas will now work with the relevant authorities to enable patient access to ACP as quickly as possible. The Company has already reflected the impact of this approval in its financial forecast of the current fiscal year ending March 31, 2026.

About avacincaptad pegol (ACP)
ACP is a synthetic aptamer that inhibits the complement C5 protein.[10] Overactivity of the complement system and the C5 protein play a critical role in the development and growth of scarring and vision loss associated with GA secondary to AMD.[10] By targeting C5, ACP is considered to decrease activity of the complement system known to cause the degeneration of retinal cells and thus slow the progression of GA.[10]

About Geographic Atrophy (GA)
GA is an advanced form of age-related macular degeneration (AMD) that leads to irreversible and progressive vision loss.[8,10,11] It affects the macula, the central portion of the retina responsible for central vision. AMD is the leading cause of visual loss in people aged over 50 years old in developed countries.[2] In Japan, an estimated 100,000 people live with GA, and no approved treatments have been available until now.[6,7]

About the GATHER Clinical Trial Program
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 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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