Press Release

Astellas Provides Update on Marketing Authorization Application for Avacincaptad Pegol (ACP) in the European Union

TOKYO, Oct 28, 2024 – Astellas Pharma Inc. (TSE: 4503, President and CEO: Naoki Okamura, "Astellas") today announced the company's decision to withdraw its marketing authorization application from the European Medicines Agency (EMA) for avacincaptad pegol intravitreal solution (ACP), an investigational synthetic aptamer that inhibits the complement C5 protein, for the treatment of geographic atrophy (GA) secondary to age-related macular degeneration (AMD).

The company's decision to withdraw its application followed interactions with the EMA's Committee for Medicinal Products for Human Use (CHMP).

Astellas maintains that the clinically meaningful benefit of ACP in slowing GA lesion growth outweighs the risks. Astellas remains confident in ACP's clinical profile and believes its capacity to slow disease is a benefit for people living with GA.

There are currently no approved treatments outside of the U.S. Astellas is fully committed to engaging with regulatory authorities to explore available options to bring ACP to patients with GA globally (including in Europe).

Marci English, Vice President, Head of BioPharma & Ophthalmology Development, Astellas
"We would like to emphasize our confidence in ACP's clinical profile as demonstrated in two randomized sham-controlled trials and its potential to benefit people living with geographic atrophy (GA).

GA is a devastating progressive disease, which leads to severe and irreversible visual impairment and blindness. As the science and understanding of GA expands, Astellas and other companies are pioneering the way to bring new treatment options to people with the disease.

While we are disappointed with the CHMP's response, we have seen the impact this medicine has had for GA patients in the U.S.[1] and remain committed to serving unmet patient needs globally."

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

About avacincaptad pegol
Avacincaptad pegol (ACP) is an investigational drug for treatment of geographic atrophy (GA) secondary to age-related macular degeneration (AMD) that is currently under evaluation for safety and efficacy by the European Medicines Agency.[2] ACP is approved in the U.S. as IZERVAY for the treatment of GA secondary to AMD.[3] ACP is a synthetic aptamer that inhibits the complement C5 protein.[3] 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.[3] By

targeting C5, ACP has the potential to decrease activity of the complement system known to cause the degeneration of retinal cells and thus slow the progression of GA.[3]

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.[4] The macula is a small area in the central portion of the retina responsible for central vision. As AMD progresses, the loss of photoreceptors and the underlying blood vessels in the macula results in marked thinning and/or atrophy of retinal tissue.[2] Geographic atrophy (GA), associated with AMD, leads to further irreversible loss of vision in these patients.[5] Globally, over five million people are estimated to have GA.[6]

About Astellas
Astellas Pharma Inc. is a pharmaceutical company conducting business in more than 70 countries around the world. Our Focus Area Approach 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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References

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3. Desai, D and Dugel, PU. Complement cascade inhibition in geographic atrophy: a review. *Eye*. 2022; 36(2):294–302.
4. Ayoub, T and Patel, N. Age-related macular degeneration. *J R Soc Med*. 2009; 102(2):56–61.
5. Patel, PJ, et al. Burden of illness in geographic atrophy: a study of vision-related quality of life and health care resource use. *Clin Ophthalmol*. 2020; 14:15–28.
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