Press Release

Iveric Bio Announces Positive 24-Month Topline Results from Phase 3 Study of IZERVAY™ (avacincaptad pegol intravitreal solution) for Geographic Atrophy

GATHER2 24-month results met the primary objective of reducing the rate of GA growth in patients treated with IZERVAY compared to sham

IZERVAY 24-month safety data were consistent with 12-month results, with no new safety signals identified

TOKYO, September 18, 2023 – Astellas Pharma Inc. (TSE: 4503, President and CEO: Naoki Okamura, "Astellas") today announced positive 24-month topline results from the Phase 3 GATHER2 clinical trial evaluating the efficacy and safety of IZERVAY™ (avacincaptad pegol intravitreal solution), a complement C5 inhibitor for the treatment of geographic atrophy (GA) secondary to age-related macular degeneration (AMD).

Topline results demonstrated that the IZERVAY monthly dosing regimen met the primary objective to significantly slow GA growth compared to sham at 24 months. Additionally, the treatment effect with the every other month dosing regimen for IZERVAY showed a similar reduction in the rate of GA growth versus sham.

Overall, safety after 24 months of treatment was consistent with previously reported 12-month data, with no new safety signals identified. There was one case of culture-positive endophthalmitis and one case of non-serious intraocular inflammation. There were no cases of occlusive or non-occlusive retinal vasculitis or ischemic neuropathy. The rate of choroidal neovascularization (CNV) was 12% in patients treated with IZERVAY and 9% in those treated with sham.

Dhaval Desai, PharmD, Senior Vice President and Chief Development Officer, Iveric Bio, An Astellas Company
"We are excited about these results, which show that IZERVAY continued to slow the rate of GA growth with a consistent safety profile after two years of treatment. We look forward to sharing results at a future scientific congress and with regulatory agencies."

IZERVAY was approved by the U.S. Food and Drug Administration on August 4, 2023, for the treatment of geographic atrophy (GA) secondary to age-related macular degeneration (AMD) and is currently under review by the European Medicines Agency.

Astellas is reviewing potential financial impacts of these results 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). The primary objective at 24 months was to demonstrate whether, after re-randomization at 12 months, ACP slowed the GA growth rate (slope) in the EM treatment arm compared to sham.

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.

About Iveric Bio
Iveric Bio, An Astellas Company, is a science-driven biopharmaceutical company focused on the discovery and development of novel treatments for retinal diseases with significant unmet medical needs. The Company is committed to having a positive impact on patients' lives by delivering high-quality, safe, and effective treatments designed to address debilitating retinal diseases including earlier stages of age-related macular degeneration. For more information on the Company, please visit www.ivericbio.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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