Iveric Bio Announces Vision Loss Reduction Data in Geographic Atrophy from Avacincaptad Pegol GATHER Trials

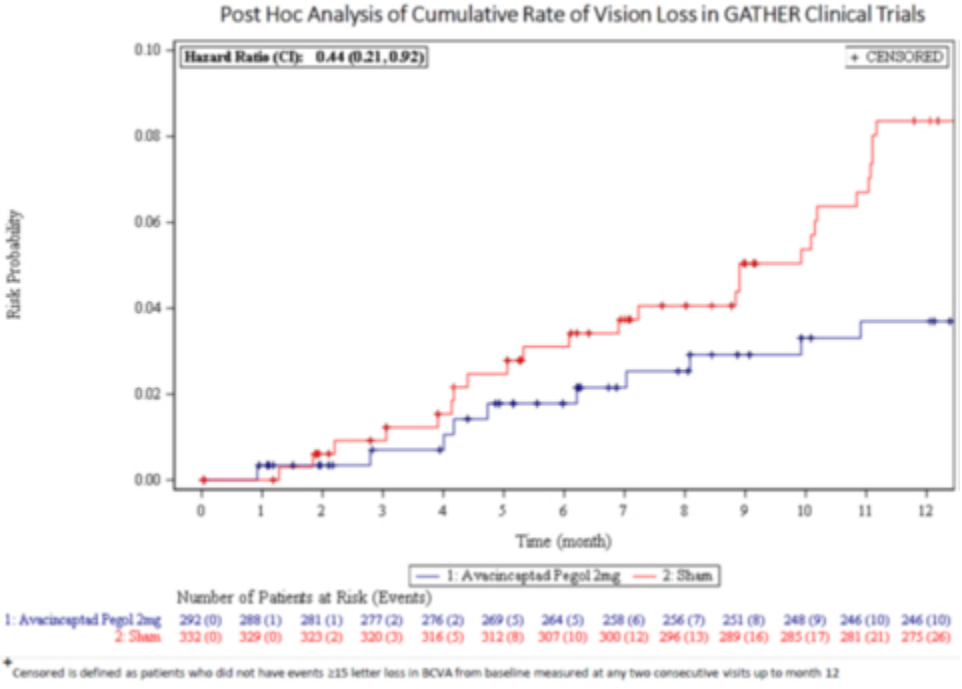
March 1, 2023

- Post-hoc time-to-event analysis signals up to 59% risk reduction in rate of vision loss compared to sham treatment at 12 months -

- Analysis to be presented at the ARVO Annual Meeting from April 23-27, 2023 -

PARSIPPANY, N.J.--(BUSINESS WIRE)--Mar. 1, 2023-- IVERIC bio, Inc. (Nasdaq: ISEE) today announced an exploratory time-to-event analysis from the avacincaptad pegol (ACP) GATHER clinical trial program evaluating reduction in vision loss with ACP 2 mg versus sham treatment. The GATHER1 and GATHER2 clinical trials were designed to evaluate the rate of geographic atrophy (GA) lesion growth in patients with GA secondary to age-related macular degeneration. The post-hoc analysis for vision loss from these pivotal studies signals up to a 59% reduction in rate of vision loss with ACP 2 mg compared to sham treatment at 12 months. Vision loss in this analysis was defined as a loss of ≥15 letters (EDTRS) in Best Corrected Visual Acuity (BCVA) from baseline measured at any two consecutive visits up to month 12. This analysis will be presented at the upcoming Association for Research in Vision and Ophthalmology (ARVO) Annual Meeting from April 23-27, 2023.

This press release features multimedia. View the full release here: https://www.businesswire.com/news/home/20230228006487/en/



Post-Hoc Analysis of Cumulative Rate of Vision in GATHER Clinical Trials (Photo: Business Wire)

Results were consistent in the GATHER1 and GATHER2 clinical trials independently, signaling a 44% reduction (Hazard Ratio 0.56 with 95% CI, 0.15-2.06) and a 59% percent reduction (Hazard Ratio 0.41 with 95% CI, 0.17-1.00) respectively in the rate of vision loss with ACP 2 mg compared to sham over the first 12 months of treatment. In a combined analysis of GATHER1 and GATHER2 shown in the accompanying graph, patients treated with ACP 2 mg experienced a 56% reduction (Hazard Ratio 0.44, with 95% CI, 0.21-0.92) in the rate of vision loss compared to sham over the first 12 months of treatment. This post-hoc analysis evaluates the potential vision loss signal through 12 months of treatment and is exploratory in nature.

“GA is a devastating disease, which can lead to vision loss and irreversible blindness taking away the patients’ ability to drive, read and see their loved ones,” says Arshad M. Khanani, MD, MA, FASRS, Managing Partner and Director of Clinical Research at Sierra Eye Associates, Reno, Nevada. “On average, it takes 2.5 years for GA lesions to start impacting central vision[1]. Early treatment effect has the potential to change the trajectory of disease for patients. A reduction in rate of vision loss with ACP 2 mg of up to 59% compared to sham treatment at 12 months supports the clinical relevance of the GATHER1 and GATHER2 primary endpoint, which met statistical significance.”

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 U.S. FDA. ACP is a novel complement C5 protein inhibitor. Overactivity of the complement system and the C5 protein are suspected to play a critical role in the development and growth of scarring and vision loss associated with GA secondary to AMD. By targeting C5, ACP has the potential to decrease activity of the complement system that causes the degeneration of retinal cells and potentially slow the progression of GA.

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

ACP met its primary endpoint in the completed GATHER1 clinical trial and the ongoing GATHER2 clinical trial, both of which are randomized, double-masked, sham-controlled, multicenter Phase 3 clinical trials. These clinical trials evaluated the safety and efficacy of monthly 2 mg intravitreal administration of ACP in patients with GA secondary to AMD. For the first 12 months in both trials, patients were randomized to receive either ACP 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. The mean rate of growth (slope) in GA area from baseline to month 12 using observed data was 35% in GATHER 1 and 18% in GATHER2. In GATHER1 and GATHER2 combined, the most frequently reported treatment emergent adverse events at 12 months in the 2 mg recommended dose were related to the injection procedure. The most common adverse reactions (≥ 5% and greater than sham) reported at 12 months in patients who received ACP 2 mg were conjunctival hemorrhage (13%), increased IOP (9%), and CNV (7%).

About Iveric Bio

Iveric Bio 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.

Forward-looking Statements

Any statements in this press release about the Company's future expectations, plans and prospects constitute forward-looking statements for purposes of the safe harbor provisions under the Private Securities Litigation Reform Act of 1995. Forward-looking statements include any statements about the Company's strategy, future operations and future expectations and plans and prospects for the Company, and any other statements containing the words "anticipate," "believe," "estimate," "expect," "intend", "goal," "may", "might," "plan," "predict," "project," "seek," "target," "potential," "will," "would," "could," "should," "continue," and similar expressions. In this press release, the Company's forward-looking statements include statements about its expectations regarding the results and implications of the clinical data from its GATHER1 and GATHER2 trials of ACP in geographic atrophy, including the relevance of post-hoc analyses from these trials, and the potential safety and efficacy of ACP in treating GA. Such forward-looking statements involve substantial risks and uncertainties that could cause the Company's development programs, future results, performance, or achievements to differ significantly from those expressed or implied by the forward-looking statements. Such risks and uncertainties include, among others, those related to expectations for regulatory matters, interpretation of clinical trial results by the scientific and medical community, developments from the Company's competitors and the marketplace for the Company's products, and other factors discussed in the "Risk Factors" section contained in the quarterly and annual reports that the Company files with the Securities and Exchange Commission. Any forward-looking statements represent the Company's views only as of the date of this press release. The Company anticipates that subsequent events and developments may cause its views to change. While the Company may elect to update these forward-looking statements at some point in the future, the Company specifically disclaims any obligation to do so except as required by law.

References

1. Lindblad AS, et al, and AREDS Research Group. Arch Ophthalmol. 2009;127(9):1168-1174

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