Iveric Bio Announces FDA Accepts New Drug Application and Grants Priority Review for Avacincaptad Pegol for the Treatment of Geographic Atrophy

February 16, 2023

- PDUFA goal date is August 19, 2023 -

PARSIPPANY, N.J.--(BUSINESS WIRE)--Feb. 16, 2023-- IVERIC bio, Inc. (Nasdaq: ISEE) today announced that the U.S. Food and Drug Administration (FDA) has completed its filing review and accepted the company's New Drug Application (NDA) for avacincaptad pegol (ACP), a novel investigational complement C5 inhibitor for the treatment of geographic atrophy (GA) secondary to Age-Related Macular Degeneration (AMD). The NDA has been granted Priority Review with a Prescription Drug User Fee Act (PDUFA) goal date of August 19, 2023. The company also announced that, at this time, the FDA has not identified any potential review issues and the FDA is not currently planning to hold an Advisory Committee meeting for ACP.

"The FDA's acceptance of our NDA and Priority Review for avacincaptad pegol bring us another significant step closer to delivering a much-needed treatment to AMD patients living with GA," said Glenn P. Sblendorio, Chief Executive Officer of Iveric Bio. "We look forward to continuing our collaboration with the FDA throughout the review process."

The NDA submission is based on the 12-month pre-specified primary efficacy and safety results from the GATHER1 and GATHER2 clinical trials. ACP is the only investigational product for the treatment of GA to achieve the pre-specified 12-month primary endpoint in two phase 3 pivotal trials with observed efficacy rates of up to 35%. In addition, ACP is the first and only investigational therapy to receive Breakthrough Therapy designation for GA secondary to AMD.

"We believe our Special Protocol Assessment for GATHER2, rolling review, Breakthrough Therapy designation and now Priority Review underscore the strength of our GATHER1 and GATHER2 results," said Pravin U. Dugel, President of Iveric Bio. "We continue to accelerate our commercial launch plans and prepare for a potential approval of ACP for the treatment of GA throughout the AMD disease continuum. This is important because AMD leads to irreversible, and in many cases catastrophic, vision loss."

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. There are currently no U.S. FDA or European Medicines Agency (EMA) approved treatment options available for patients with geographic atrophy secondary to AMD.

About Avacincaptad Pegol

Avacincaptad pegol (ACP) is an investigational drug 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 geographic atrophy (GA) secondary to age-related macular degeneration (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 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 in the 2 mg recommended dose were related to injection procedure. The most common adverse reactions (≥ 5% and greater than sham) reported in patients who received avacincaptad pegol 2 mg were conjunctival hemorrhage (13%), increased IOP (9%), and CNV (7%). After 18 months of treatment in GATHER1 and 12 months of treatment in GATHER2, there were no events of serious intraocular inflammation, vasculitis, or endophthalmitis.

About Priority Review

Priority Review designation means FDA's goal is to take action on a drug application within six months of application acceptance compared to ten months under Standard Review. Priority Review designation will direct overall attention and resources to the evaluation of applications for drugs that, if approved, would be significant improvements in the safety or effectiveness of the treatment, diagnosis, or prevention of serious conditions when compared to standard applications.[1]

About FDA Filing Review

The goal of the FDA's filing review is to determine whether an application, on its face, is sufficiently complete to permit a substantive review. The filing review is only a preliminary evaluation of the NDA and is not indicative of deficiencies that may be identified during the review process.

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, its development and regulatory strategy for ACP, including expectations for the review of its NDA for ACP in GA and potential for approval, and the potential utility 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. U.S. Food and Drug Administration. Priority Review. January 4, 2018. Available at https://www.fda.gov/patients/fast-track-breakthrough-therapy-accelerated-approval-priority-review/priority-review. Last accessed: February 2023.

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