Iveric Bio Announces Completion of Rolling NDA Submission to FDA for Avacincaptad Pegol for the Treatment of Geographic Atrophy

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- Commercial launch preparations continue to accelerate -

PARSIPPANY, N.J.--(BUSINESS WIRE)--Dec. 20, 2022-- IVERIC bio, Inc. (Nasdaq: ISEE) today announced that it has submitted to the U.S. Food and Drug Administration (FDA) the third and final part of its New Drug Application (NDA) for rolling review of avacincaptad pegol (ACP), a novel investigational complement C5 inhibitor for the treatment of geographic atrophy (GA) secondary to Age-Related Macular Degeneration (AMD). Per the company's agreement with the FDA for rolling NDA review, part 3 of the NDA included chemistry, manufacturing, and controls data.

"We are excited to have submitted our complete NDA for avacincaptad pegol with a request for priority review based on our Breakthrough Therapy designation," said Glenn P. Sblendorio, Chief Executive Officer of Iveric Bio. "We continue to accelerate our launch preparations with the goal of making a treatment available as soon as possible for AMD patients impacted by GA, a disease that leads to irreversible blindness."

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 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 are thrilled with the statistically significant efficacy and consistent safety results from both the GATHER1 and GATHER2 pivotal clinical trials," said Pravin U. Dugel, President of Iveric Bio. "Our Special Protocol Assessment Agreement for GATHER2, rolling review, Breakthrough Therapy designation and priority review request are intended to expedite the review process and get avacincaptad pegol to GA patients, who currently have no treatment options. We look forward to collaborating with the FDA throughout the NDA review process."

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 has not yet been evaluated by any regulatory body for safety and efficacy. ACP is not authorized for any indication in any country. 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 measured the efficacy and safety 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 Breakthrough Therapy Designation
Breakthrough Therapy designation is a process designed to expedite the development and review of drugs that are intended to treat a serious condition and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over available therapy on a clinically significant endpoint(s). The FDA will review the full data submitted to support approval of drugs designated as breakthrough therapies to determine whether the drugs are safe and effective for their intended use before they are approved for marketing.

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 priority review of its submitted NDA for ACP in GA and potential for approval, and the potential utility of ACP in treating geographic atrophy. 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.

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