Iveric Bio Announces the Addition of Pravin U. Dugel, MD, to its Board of Directors

January 3, 2023

PARSIPPANY, N.J.--(BUSINESS WIRE)--Jan. 3, 2023-- IVERIC bio, Inc. (Nasdaq: ISEE) announced today the election of Pravin U. Dugel, MD, President of Iveric Bio, to its Board of Directors, effective as of January 1, 2023. Dr. Dugel has been instrumental in helping to shape the Company's business strategy and in overseeing the development and regulatory submission process for avacincaptad pegol (ACP, also known as Zimura®) since he joined Iveric Bio in 2020.

"On behalf of the entire Board of Directors, we are excited to have Pravin join our board during this pivotal time as the Company prepares for a potential approval and commercial launch of ACP in geographic atrophy," stated Adrienne L. Graves, PhD, Chairman of the Board of Iveric Bio.

"Pravin is an exceptional leader whose skills as an executive and extensive knowledge as a retinal specialist provide a valued perspective that will enhance the collective experience of our Board," stated Glenn P. Sblendorio, Chief Executive Officer of Iveric Bio. "I enjoy working closely with Pravin and now look forward to working with him in his added role as a board member. We are committed to executing our plan to deliver value to our shareholders."

"I look forward to adding to my responsibilities by serving as a board member of the Company and I am particularly honored to be among this group of talented and diverse board members," stated Pravin U. Dugel, MD, President of Iveric Bio. "Following the successful results from our Phase 3 ACP clinical trials, I believe we have the potential to transform the AMD treatment landscape by bringing a breakthrough therapy to patients impacted by geographic atrophy."

Pravin U. Dugel, MD

Dr. Dugel is currently the President of Iveric Bio. He joined as Executive Vice President in April 2020 and was promoted to President of the Company in May 2021. Dr. Dugel has over 26 years of experience as a retina specialist. Dr. Dugel was previously Managing Partner, Retinal Consultants of Arizona and the Retinal Research Institute; Clinical Professor, USC Eye Institute, Keck School of Medicine, University of Southern California; and Founding Member, Spectra Eye Institute in Sun City, Arizona. Dr. Dugel has authored more than 200 papers, 35 book chapters and has been invited to lecture at several marquis medical meetings and to serve as a visiting professor at universities worldwide, including in Japan, India, China, Malaysia, Egypt, the United Kingdom, France, Germany, Austria, Italy, Poland, Denmark, Norway, Czechoslovakia, Canada and Australia. Dr. Dugel is internationally recognized as a major clinical researcher and has been a principal investigator in over 100 multicenter clinical trials. His research and educational contributions earned him the prestigious Senior Honor Award from the American Academy of Ophthalmology (AAO). He has been elected and previously served as the Retina Subspecialty Day Board Chairman for the American Academy of Ophthalmology Annual Meeting, as a member of the Board of Directors of the largest retina society in the United States, the American Society of Retina Specialists (ASRS), and the largest retina society in Europe, EURETINA.

Dr. Dugel graduated summa cum laude from Columbia University in New York City. He then attended UCLA School of Medicine. He completed his residency in ophthalmology at the USC Eye Institute, Keck School of Medicine. Thereafter, he completed his medical retina fellowship at the Bascom Palmer Eye Institute and his surgical retina fellowship at the USC Eye Institute, where he was elected to serve on the faculty as the Resident Director.

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, the advanced stage of 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 its development and regulatory strategy for ACP, the impact of FDA designations and the potential approvability and timelines for review of ACP, 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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