Iveric Bio Completes Patient Enrollment of GATHER2 Pivotal Clinical Trial of Zimura® Ahead of Schedule

July 26, 2021

- Topline Data Expected in 2H 2022; if Positive, New Drug Application Expected -

NEW YORK--(BUSINESS WIRE)--Jul. 26, 2021-- IVERIC bio, Inc. (Nasdaq: ISEE) today announced the early completion of patient enrollment of GATHER2, the Company's second pivotal clinical trial of Zimura ® (avacincaptad pegol) in development for the treatment of geographic atrophy (GA) secondary to age-related macular degeneration (AMD). The Company expects topline GATHER2 data to be become available during the second half of 2022, approximately one year after the enrollment of the last patient, plus the time needed for database lock and analysis.

"The time to complete enrollment in the Zimura GATHER2 clinical trial was four months ahead of our original timeline. That we were able to accomplish this during the unprecedented challenges stemming from the global COVID-19 pandemic, we believe highlights the unmet need of patients and physicians for a treatment of GA secondary to AMD," stated Glenn P. Sblendorio, Chief Executive Officer of Iveric Bio. "Patient retention continues to exceed our expectations in GATHER2. We look forward to sharing the topline results of GATHER2 in the second half of 2022 and to the potential opportunity to bring Zimura therapy to GA secondary to AMD patients around the world."

In June 2021, the Company announced that it is targeting patient retention for the trial, as measured by the injection fidelity rate through month 12, of greater than 90%. Injection fidelity is calculated by dividing the total number of actual injections by the total number of expected injections based on the number of enrolled patients. The Company considers injection fidelity to be the most important component of patient retention because it reflects the timely administration of the drug into the patient's eye.

The Company also announced earlier this month that it received written agreement from the U.S. Food and Drug Administration (FDA) under a Special Protocol Assessment (SPA) for the overall design of GATHER2. The agreement further solidifies the Company's plans to file an application with the FDA for marketing approval of Zimura for GA secondary to AMD, if the ongoing GATHER2 clinical trial meets its primary endpoint at 12 months. Zimura met its pre-specified primary efficacy endpoint at 12 months and reached statistical significance in the previously completed GATHER1 pivotal clinical trial.

"The successful completion of enrollment ahead of schedule and on-going patient retention in GATHER2 reflect the tremendous work and innovative programs our clinical team has executed and are a tribute to our patients, investigators and their study staff," stated Pravin U. Dugel, President of Iveric Bio. "This milestone would have been impressive at any time however it is more impressive during a global pandemic. We continue to focus on retention, not only to protect the integrity of our data, but also with the goal of demonstrating Zimura's early and continuous treatment effect over time, similar to what we observed previously in GATHER1."

In GATHER2, 448 patients were randomized to receive either monthly administration of Zimura 2 mg or sham during the first 12 months of the trial, at which time the primary efficacy analysis of the mean rate of change of GA growth (slope) at 12 months will be performed. If the 12 month results are positive, the Company plans to file an application with the U.S. Food and Drug Administration and the European Medicines Agency for marketing approval of Zimura for GA following receipt of that data. At month 12, the Company plans to re-randomize patients in the Zimura 2 mg arm to receive either monthly or every other month administration of Zimura 2 mg. The final evaluation will take place at month 24.

About Zimura

Zimura (avacincaptad pegol) is an investigational drug product and has not been approved for use anywhere globally. Zimura is designed to target and inhibit the cleavage of complement protein C5 and the formation of its downstream fragments, C5a and C5b. By inhibiting the formation of these fragments, Zimura is believed to decrease or slow the chronic inflammation and cell death associated with the retinal aging process by decreasing the formation of membrane attack complex (MAC) and inflammasome activity, thereby potentially avoiding or slowing the degeneration of retinal pigment epithelial cells. This potential mechanism is the rationale for Zimura as a potential therapy for geographic atrophy secondary to age-related macular degeneration.

About Iveric Bio

Iveric Bio is a science-driven biopharmaceutical company focused on the discovery and development of novel treatment options for retinal diseases with significant unmet medical needs. The Company is currently developing both therapeutic product candidates for age-related retinal diseases and gene therapy product candidates for orphan inherited retinal diseases. 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 the Company's development and regulatory strategy for Zimura, including its strategy to seek marketing approval from the FDA and EMA for Zimura for the treatment of GA secondary to AMD if the ongoing GATHER2 clinical trial meets its primary endpoint at 12 months, the timing,

progress and results of clinical trials, including expectations regarding patient retention in, and the availability of topline data from, GATHER2, and other research and development activities and the potential utility of Zimura. 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, the progression and duration of the COVID-19 pandemic and responsive measures thereto and related effects on the Company's research and development programs, operations and financial position, the initiation and the progress of research and development programs and clinical trials, availability of data from these programs, reliance on clinical trial sites, contract research organizations and other third parties, establishment of manufacturing capabilities, need for additional financing and negotiation and consummation of business development transactions 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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