Iveric Bio Announces First Patient Dosed in Second Zimura® Phase 3 Clinical Trial for the Treatment of Geographic Atrophy Secondary to Age-Related Macular Degeneration

June 30, 2020

NEW YORK--(BUSINESS WIRE)--Jun. 30, 2020-- IVERIC bio, Inc. (Nasdaq: ISEE) today announced the first patient has been dosed in GATHER2, also known as ISEE2008, the second Phase 3 clinical trial for Zimura® (avacincaptad pegol), a novel complement C5 inhibitor, in development for the treatment of geographic atrophy (GA) secondary to age-related macular degeneration (AMD). The Company announced previously that Zimura met its pre-specified primary efficacy endpoint and reached statistical significance in GATHER1, also known as OPH2003, the first Phase 3 clinical trial for Zimura for the treatment of GA secondary to AMD. There are no U.S. Food and Drug Administration or European Medicines Agency approved treatments available for patients with GA secondary to AMD.

"The absence of treatment options for geographic atrophy represents an area of urgent unmet medical need and a major public health concern for the expanding aging population," stated Glenn P. Sblendorio, Chief Executive Officer and President of IVERIC bio. "The initiation of enrollment in GATHER2, brings us another step closer to potentially delivering a clinically meaningful therapy to patients with GA. The GATHER2 clinical trial, if positive, marks the second Phase 3 clinical trial needed to seek regulatory approval for Zimura."

"We believe GATHER1 is currently the only Phase 3 clinical trial showing early suppression of GA growth which continued for 18 months with continuous treatment," stated Kourous A. Rezaei, M.D., Chief Medical Officer of IVERIC bio. "We have experienced impressive enthusiasm by our investigators to initiate the second Phase 3 trial, GATHER2, based on the robustness of efficacy, the strength of the statistical evidence, and the favorable safety profile of Zimura in the GATHER1 Phase 3 trial. We believe that these robust data increase comfort and confidence in our investigators to expedite recruitment and retain patients in our GATHER2 clinical trial."

In the GATHER2 clinical trial, approximately 400 patients will be 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 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.

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. Food and Drug Administration (FDA) or European Medicines Agency (EMA) approved treatment options available for patients with geographic atrophy.

Zimura

Complement factor C5 is a central component of the complement cascade and is believed to be involved in the development and progression of AMD. Zimura is designed to inhibit complement factor C5 cleavage into C5a and C5b. By inhibiting the formation of complement C5 terminal fragments, Zimura may decrease the activation of inflammasomes and the formation of membrane attack complex (MAC). This mechanism of action could potentially prevent or slow down the degeneration of retinal pigment epithelial (RPE) cells and slow down the progression of GA.

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. Vision is Our Mission. 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 impact of the COVID-19 pandemic on the Company's research and development programs, operations and financial position, its expectations to initiate enrollment in its second Phase 3 trial (GATHER2) of Zimura in geographic atrophy secondary to AMD and to use its previously announced clinical trial of Zimura for the treatment of geographic atrophy (GATHER1) as a Phase 3 trial, its development and regulatory strategy for Zimura, the potential clinical meaningfulness of the results of clinical trials, the Company's hypotheses regarding complement inhibition as a mechanism of action for the treatment of geographic atrophy, the implementation of its business plan, the timing, progress and results of clinical trials and other research and development activities and the potential utility of its product candidates. 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 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 collaborators and other third parties, establishment of manufacturing capabilities, expectations for regulatory matters and need for additional financing 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 will 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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Investor Contact:
IVERIC bio
Kathy Galante, 212-845-8231
Vice President, Investor Relations and Corporate Communications
kathy.galante@ivericbio.com

or

Media Contact:
SmithSolve
Alex Van Rees, 973-442-1555 ext. 111
alex.vanrees@smithsolve.com

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