Iveric Bio Announces Design for Second Pivotal Clinical Trial of Zimura® in Geographic Atrophy Secondary to Dry Age-Related Macular Degeneration

January 13, 2020

- On-Track for First Patient Enrollment in 1Q 2020–

-Company to Host R&D Symposium for Investors/Analysts on Tuesday January 14, 2020 in San Francisco, CA from 6:30 to 8:00 am (Pacific Time) -

NEW YORK--(BUSINESS WIRE)--Jan. 13, 2020-- IVERIC bio, Inc. (Nasdaq: ISEE) today announced the design of the second pivotal clinical trial for Zimura® (avacincaptad pegol), a novel complement C5 inhibitor, in development for the treatment of geographic atrophy (GA) secondary to dry age-related macular degeneration (AMD). This second pivotal trial will be an international, multicenter, double masked, sham controlled clinical trial. The Company plans to enroll approximately 400 patients to be randomized to receive monthly administration of Zimura 2 mg or sham during the first 12 months of the trial. The prespecified primary endpoint, mean rate of change in GA growth over 12 months, will be measured by fundus autofluorescence (FAF) based on readings at three time points (baseline, month 6, and month 12) consistent with the previous Zimura pivotal clinical trial design. 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.

“This trial is our top priority and we are working to address this major unmet medical need where there are no approved treatment options available for the approximately 1.5 million patients living with geographic atrophy in the US alone,” stated Glenn P. Sblendorio, Chief Executive Officer and President of IVERIC bio.

“Based on the positive 12-month results from our first pivotal trial for Zimura in GA we are looking forward to enrolling our first patient in our second pivotal clinical trial,” stated Kourous A. Rezaei, M.D., Chief Medical Officer of IVERIC bio. “In the first trial, both the Zimura 2 mg and Zimura 4 mg doses met the primary efficacy endpoint at month 12 with statistical significance and similar efficacy as compared to sham. Since Zimura 2 mg is administered as a single intravitreal injection, as compared to two intravitreal injections for Zimura 4 mg, the upcoming trial will compare the safety and efficacy of the Zimura 2 mg dose to sham control in patients with GA. Our goal is to enroll the first patient in the first quarter of 2020.”

On October 28, 2019, the Company announced that Zimura met its pre-specified primary efficacy endpoint and reached statistical significance in an international, multicenter, randomized, double masked, sham-controlled clinical trial in GA secondary to dry AMD. Zimura was generally well tolerated after 12 months of administration. IVERIC bio provided further details supporting the positive results from this trial, which the Company plans to use as a pivotal trial, in its Quarterly Report on Form 10-Q filed on November 12, 2019.

R&D Symposium for Investors/Analysts

The Company will host an R&D Symposium for Investors/Analysts on Tuesday, January 14, 2020 from 6:30a.m. to 8:00a.m. Pacific Time in San Francisco, CA. The event will feature a presentation on the Zimura pivotal program in GA secondary to dry AMD with details on the design followed by additional presentations on statistical analysis and the primary endpoint for the program.

The event will be accessible via webcast on the IVERIC bio website at www.ivericbio.com. For more information, please contact Kathy Galante at kathy.galante@ivericbio.com or 212-845-8231.

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 dry AMD. Zimura is designed to target and inhibit complement factor C5. Zimura binds to C5 and inhibits its cleavage into the terminal fragments, C5a and C5b. By inhibiting the formation of complement system terminal fragments, Zimura may decrease the activation of inflammasomes and the formation of membrane attack complex (MAC), which occur at the end of the complement cascade. This mechanism of action could potentially prevent or slow down the degeneration of retinal pigment epithelial (RPE) cells providing the potential therapeutic rationale in GA secondary to dry AMD.

IVERIC bio

IVERIC bio is a biopharmaceutical company focused on the discovery and development of novel treatment options for retinal diseases with significant unmet medical needs. 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 its expectations to use its previously announced clinical trial of Zimura for the treatment of geographic atrophy as a pivotal trial, its development strategy for Zimura, the projected use of cash and cash balances, the timing, progress and results of clinical trials and other research and development activities, the potential utility of its product candidates, estimates regarding the number of patients affected by the diseases and indications the Company's product candidates are intended to treat and the potential for its business development strategy. 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 initiation and the progress of research and development programs and clinical trials, availability of data from these programs, reliance on university collaborators and other third parties, establishment of manufacturing capabilities, expectations for regulatory matters, 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 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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