Iveric Bio Reports First Quarter 2022 Operational Highlights and Financial Results

May 4, 2022

- Zimura® GATHER2 Topline Data Expected in the Third Quarter of this Year-

- GATHER2 Trial Completion at 94% for Year One; Patient Retention Continues to Exceed Expectations with a Target 12-Month Injection Fidelity Rate of Greater than 90% –

- U.S. Patent Covering Methods of Treating GA with Zimura Granted by USPTO –

- Conference Call and Webcast Today, May 4, 2022, at 8:00 a.m. ET –

PARSIPPANY, N.J.--(BUSINESS WIRE)--May 4, 2022-- IVERIC bio, Inc. (Nasdaq: ISEE) today announced financial and operating results for the first quarter ended March 31, 2022 and provided a general business update.

"During the first quarter, we continued the momentum of 2021 for GATHER2, our second Phase 3 clinical trial for Zimura ® (avacincaptad pegol), a novel complement inhibitor, for the treatment of geographic atrophy (GA)," stated Glenn P. Sblendorio, Chief Executive Officer of Iveric Bio. "We look forward to the exciting opportunities that lie ahead in 2022, including reporting topline data from GATHER2 and being closer to reaching our goal of providing patients and physicians with a treatment for GA for which there are currently no treatments options available."

- The Company expects topline GATHER2 data to be available in the third quarter of this year, approximately one year after the enrollment of the last patient plus the time needed for database lock and analysis. If the results from GATHER2 are positive, the Company plans to submit a new drug application (NDA) with the U.S. Food and Drug Administration (FDA) and a marketing authorization application (MAA) with the European Medicines Agency.
- Patient retention for the GATHER2 clinical trial, as measured by the injection fidelity rate, continues to exceed the Company's expectations. The Company is targeting an injection fidelity rate for GATHER2, as measured through month 12, of greater than 90%. Injection fidelity is calculated by dividing the total number of actual injections (drug and sham) for all patients by the total number of expected injections (drug and sham) based on the total number of patients enrolled in the trial. The Company considers injection fidelity to be the most important and stringent measure of patient retention because it reflects the timely administration of the drug or sham into the patient's eye.
- The Company is currently more than 94% complete with year one of the GATHER2 clinical trial, based on the number of scheduled patient visits.

"We are pleased with the strength of our current cash position and with the progress achieved during this first quarter," stated Pravin U. Dugel, MD, President of Iveric Bio. "As we get closer to reporting the GATHER2 topline data, we continue to prepare for a potential submission of an NDA in the U.S. for Zimura for the treatment of GA as efficiently as possible. We are well-positioned with an established medical affairs team in place, and we continue to build out our commercial infrastructure with a team that has extensive experience in launching drugs to treat retinal diseases with large market potential. Additionally, during this year we continue to provide additional exploratory analyses from GATHER1, our first pivotal clinical trial for Zimura in GA, which analyses we believe further support the consistency of the positive data previously reported for GATHER1 and inform future potential development opportunities for Zimura in other indications."

Zimura® (avacincaptad pegol): Complement C5 Inhibitor

- Today, the Company provided results from a post-hoc analysis of GATHER1 evaluating the reduction in GA lesion growth observed for patients receiving Zimura as compared to patients receiving sham in a subset of patients based on the distance of a patient's GA lesion to the foveal center at baseline. See the press release issued earlier today. The Company believes the results of this post-hoc analysis are consistent with the other results previously reported for GATHER1.
- In March 2022, the U.S. Patent and Trademark Office (USPTO) granted the Company a patent with claims covering methods of using Zimura for the treatment of GA. Subject to any patent term adjustments or extensions the Company may obtain, the issued patent is expected to expire in 2034.
- In April 2022, the Company provided results from a post-hoc analysis of the 8 cases of choroidal neovascularization (CNV) reported for the Zimura 2 mg group (n=67 patients) in the GATHER1 trial. An independent and masked reading center reviewed the optical coherence tomography (OCT) images of those patients at the 12-month and 18-month timepoints and classified the cases as non-exudative macular neovascularization (MNV) (2 cases at 12 months and 18 months) and

exudative MNV (4 cases at 12 months and 6 cases at 18 months). The reading center also found that among the 6 patients who developed exudative MNV at 18 months, 5 of those patients had a double layer sign at baseline. See the Company's Form 8-K filed on April 4, 2022, for full results from this analysis. Based on scientific literature and clinical understanding among the retinal community, the Company believes that the presence of a double-layer sign on OCT may be a useful biomarker to predict the future onset of cases of exudative MNV.

- In February 2022, results from a post-hoc analysis that evaluated various GA growth parameters to explore the rate of disease progression within various regions in the fovea among a subset of patients from GATHER1 were presented at the Angiogenesis, Exudation and Degeneration conference. Consistent with the overall results of GATHER1, in the post-hoc analysis a reduction in lesion growth in five standardized regions surrounding and including the central foveal area was observed for patients receiving Zimura 2 mg as compared to patients receiving sham over a period of 18 months. The Company believes preserving the central fovea region may be associated with clinical outcomes important to GA patients.

- The Company plans to initiate a clinical trial studying Zimura in patients with intermediate AMD in the fourth quarter of 2022, following planned interactions with the FDA and other regulatory authorities. The Company's development strategy in this indication is subject to regulatory feedback.

- Patient enrollment in STAR, the Company's Phase 2b screening clinical trial of Zimura for the treatment of autosomal recessive Stargardt disease (STGD1), is ongoing. The results of this clinical trial are expected after the topline results of GATHER2.

IC-500: HtrA1 (high temperature requirement A serine peptidase 1 protein) Inhibitor

- The Company is planning for IND-enabling toxicology studies for IC-500. The Company expects to submit an investigational new drug application (IND) to the FDA for IC-500 during mid-2023.

Gene Therapy Programs in Orphan Inherited Retinal Diseases (IRDs)

- As the Company focuses its efforts and resources on the development and potential commercialization of Zimura, the Company is exploring potential collaborations for the future development and potential commercialization of IC-100, the Company's product candidate for Rhodopsin-Mediated Autosomal Dominant Retinitis Pigmentosa (RHO-adRP) and IC-200, the Company's product candidate for BEST1-Related IRDs.
- The Company is continuing its minigene programs for Leber's Congenital Amaurosis type 10 (CEP290), autosomal recessive Stargardt Disease (ABCA4) and Usher's syndrome (USH2A).

Corporate Updates

The Company expanded its Board of Directors by adding Christine Ann Miller, a pharmaceutical veteran, to the Company's board of directors in January 2022.

First Quarter 2022 Financial Update and 2022 Cash Guidance

- As of March 31, 2022, the Company had approximately $345.7 million in cash, cash equivalents and available-for-sale securities.

- The Company estimates its year-end 2022 cash, cash equivalents and available-for-sale securities to range between $215 and $225 million. The Company also estimates that its cash, cash equivalents and available-for-sale securities will be sufficient to fund its planned capital expenditure requirements and operating expenses through at least mid-2024. These estimates are based on the Company's current business plan, including the continuation of its ongoing clinical development programs for Zimura in GA and STGD1 and the initiation of an intermediate AMD clinical trial, preparation and potential filing of an NDA and MAA for Zimura in GA, continuing preparations for potential commercial launch of Zimura in GA, investing in sustained release delivery technologies for Zimura, and the advancement of its IC-500 development program. Excluded from these estimates are any potential approval or sales milestones payable to Archemix Corp. or any potential expenses for actual commercial launch of Zimura, such as associated sales force expenses, any additional expenditures related to potentially studying Zimura in indications outside of GA, STGD1 and intermediate AMD, or resulting from the potential in-licensing or acquisition of additional product candidates or technologies, or any associated development the Company may pursue.

2022 Q1 Financial Highlights

- **R&D Expenses**: Research and development expenses were $22.6 million for the quarter ended March 31, 2022, compared to $18.5 million for the same period in 2021. Research and development expenses increased primarily due to the continued progress and patient recruitment activities of our GATHER2 clinical trial, increased manufacturing activities for Zimura, and increases in personnel costs, including share-based compensation associated with additional research and

development staffing.

- **G&A Expenses**: General and administrative expenses were $12.1 million for the quarter ended March 31, 2022, compared to $8.3 million for the same period in 2021. General and administrative expenses increased primarily due increases in personnel costs, including share-based compensation associated with preparations for potential commercial launch of Zimura in GA.

- **Net Loss**: The Company reported a net loss for the quarter ended March 31, 2022 of $34.5 million, or ($0.29) per diluted share, compared to a net loss of $26.8 million, or $(0.29) per diluted share, for the same period in 2021.

Conference Call/Web Cast Information

Iveric Bio will host a conference call/webcast to discuss the Company's financial and operating results and provide a business update. The call is scheduled for May 4, 2022, at 8:00 a.m. Eastern Time. To participate in this conference call, dial 1-888-317-6003 (USA) or 1-412-317-6061 (International), passcode 1313914. A live, listen-only audio webcast of the conference call can be accessed on the Investors section of the Iveric Bio website at www.ivericbio.com. A replay will be available approximately two hours following the live call for two weeks. The replay number is 1-877-344-7529 (USA Toll Free), passcode 9999784.

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.

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 availability of topline data from and patient retention in its second Phase 3 trial (GATHER2) of Zimura in geographic atrophy secondary to AMD, its ability to use its completed clinical trial of Zimura for the treatment of geographic atrophy secondary to AMD (GATHER1) as a Phase 3 trial for purposes of seeking regulatory approval, its development and regulatory strategy for Zimura and its other product candidates, including its plans to submit a new drug application to the U.S. Food and Drug Administration and a marketing authorization application to the European Medicines Agency for Zimura if the results from GATHER2 are positive, and its plans for initiating a clinical trial studying Zimura in patients with intermediate AMD, the timing, progress and results of clinical trials and other research and development activities and regulatory submissions, including the submission of an investigational new drug application for IC-500, the potential utility of its product candidates, the Company's hypotheses regarding the role of complement inhibition in potentially treating AMD, the clinical meaningfulness of clinical trial results and data, including the retrospective analyses that the Company performed on data from GATHER1, the prosecution and utility of patents and other intellectual property rights, the implementation of its business and hiring plan, its projected use of cash, cash equivalents and marketable securities and the sufficiency of its cash resources, and statements regarding the Company's business development strategy and its personnel and human capital resources. 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 other macroeconomic events and responsive measures thereto and related effects on the Company's research and development programs, operations and financial position, expectations for regulatory matters, the initiation, progress and success of research and development programs and clinical trials, including enrollment and retention in clinical trials, availability of data from these programs, reliance on clinical trial sites, contract development and manufacturing organizations and other third parties, establishment of manufacturing capabilities, developments from the Company's competitors, the scientific and medical community and the marketplace for the Company's products, human capital 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 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.

IVERIC bio, Inc.
Selected Financial Data (unaudited)
(in thousands, except per share data)

	Three Months Ended March 31,	
	2022	**2021**
Statements of Operations Data:		
Operating expenses:		
Research and development	$ 22,557	$ 18,549
General and administrative	12,113	8,322
Total operating expenses	34,670	26,871
Loss from operations	(34,670)	(26,871)

Interest income	133	77
Other income (expense), net	1	(1)
Loss before income tax benefit	(34,536)	(26,795)
Income tax benefit	-	-
Net loss	$ (34,536)	$ (26,795)
Net loss per common share:		
Basic and diluted	$ (0.29)	$ (0.29)
Weighted average common shares outstanding:		
Basic and diluted	118,755	93,311

	March 31, 2022	December 31, 2021
	(in thousands)	
Balance Sheets Data:		
Cash, cash equivalents and marketable securities	$ 345,663	$ 381,749
Total assets	$ 352,705	$ 389,358
Total liabilities	$ 19,551	$ 28,830
Additional paid-in capital	$ 1,047,563	$ 1,040,098
Accumulated deficit	$ (714,131)	$ (679,595)
Total stockholders' equity	$ 333,154	$ 360,528

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