Iveric Bio Reports Fourth Quarter and Full Year 2021 Operational Highlights and Financial Results

February 24, 2022

- Zimura® GATHER2 Topline Data Expected in the Second Half of 2022 -

- GATHER2 Trial Completion at 84% for Year One; Patient Retention Continues to Exceed Expectations with a 12-Month Injection Fidelity Rate Target Greater than 90% –

- Internal Efforts for Preparation of a New Drug Application (NDA) Ongoing -

- Zimura Phase 3 Clinical Trial for Intermediate AMD to Initiate in Second Half of 2022 –

- Conference Call and Webcast Today, February 24, 2022, at 8:00 a.m. ET –

PARSIPPANY, N.J.--(BUSINESS WIRE)--Feb. 24, 2022-- IVERIC bio, Inc. (Nasdaq: ISEE) today announced financial and operating results for the fourth quarter and full year ended December 31, 2021 and provided a general business update.

“In 2021, we successfully achieved a number of major milestones that we believe have laid the groundwork for 2022 to be a banner year for Iveric Bio,” stated Glenn P. Sblendorio, Chief Executive Officer of Iveric Bio. “We continue to focus on execution as evidenced by GATHER2, our second Phase 3 clinical trial for Zimura® (avacincaptad pegol), a novel complement inhibitor, for the treatment of geographic atrophy (GA), which continues to exceed expectations with a 12-month injection fidelity rate target of greater than 90%, despite a global pandemic. We are excited to be more than 84% complete with year one of the trial, based on the number of scheduled patient visits. We look forward to sharing topline GATHER2 data in the second half of this year, approximately one year after the enrollment of the last patient plus the time needed for database lock and analysis.”

“This is a pivotal time for the Company as we continue our internal efforts to prepare for a potential filing of a New Drug Application (NDA) for Zimura for the treatment of GA,” stated Pravin U. Dugel, MD, President of Iveric Bio. “We continue to gain momentum in building out our medical affairs and commercial infrastructure as we prepare for the potential launch of Zimura in the US. We plan to initiate a Phase 3 clinical trial studying Zimura in patients with intermediate AMD during the second half of this year. We are pursuing additional lifecycle initiatives, including evaluating multiple sustained-release delivery technologies for Zimura. Further, the U.S. Patent and Trademark Office (USPTO) recently allowed claims for a patent covering methods of treating GA with Zimura, an important addition to our intellectual property portfolio.”

Therapeutics Programs Targeting Geographic Atrophy (GA) and other Stages of Age-Related Macular Degeneration (AMD)

Zimura® (avacincaptad pegol): Complement C5 Inhibitor

- In February 2022, the USPTO allowed claims for methods of using Zimura for the treatment of GA. The patent, when issued, is expected to expire in 2034.
- 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 in a subset of patients from GATHER1, the Company’s Phase 3 clinical trial for the treatment of Zimura in GA, were presented at the Angiogenesis, Exudation and Degeneration conference. Consistent with the overall results of GATHER1, in the new 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. We believe the preservation of the central fovea region that was observed in this post-hoc analysis has the potential to be a corollary to a functional benefit.
- In July 2021, the Company announced the completion of patient enrollment in GATHER2, four months ahead of the Company’s original schedule.
- In July 2021, the Company received a 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 NDA with the FDA for marketing approval of Zimura for GA, if the ongoing GATHER2 clinical trial meets its primary endpoint at 12 months. Zimura met its pre-specified primary efficacy endpoint at 12 months with statistical significance in the previously completed GATHER1 pivotal clinical trial.
- In June 2021, the Company announced data from post-hoc analyses from the GATHER1 trial, in which the Company evaluated the progression of incomplete Retinal Pigment Epithelial and Outer Retinal Atrophy (iRORA) to complete Retinal Pigment Epithelial and Outer Retinal Atrophy (cRORA) and the progression of drusen to iRORA or cRORA, in patients receiving Zimura 2 mg as compared to patients in the corresponding sham group. Based on the Company’s hypothesis

regarding complement inhibition as a mechanism of action to treat AMD and the results of the analyses, the Company plans to initiate a Phase 3 clinical trial studying Zimura in patients with intermediate AMD in the second half of 2022. The development strategy in this indication is subject to regulatory feedback, which the Company plans to obtain before initiating this trial.

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

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

- In 2021, the Company initiated a number of preclinical tolerability and pharmacokinetic studies for IC-500. The Company anticipates that the start of IND-enabling toxicology studies for IC-500 will be later than originally planned, primarily due to the limited availability of study slots at contract research organizations in the wake of the COVID-19 pandemic. 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.

- In the second half of 2021, the Company transitioned the Stargardt Disease (ABCA4) and USH2A minigene research programs from the University of Massachusetts Medical School (UMMS) to the Company with plans to continue these programs internally. The Company has established a laboratory for continuing the work on its minigene research programs and other preclinical ocular research activities.

Corporate Updates

The Company expanded its Board of Directors and management by adding a number of industry leaders:

- Christine Ann Miller, a pharmaceutical veteran, joined the Company's board of directors in January 2022.
- Tony Gibney joined the Company as Executive Vice President and Chief Business and Strategy Officer in December 2021. Mr. Gibney is an experienced biotechnology executive and former investment banker.
- Christopher Simms joined the Company as Senior Vice President and Chief Commercial Officer in August 2021. Mr. Simms has commercial leadership experience in retina, ophthalmology, and optometry.

In October 2021, the Company raised approximately $163 million in net proceeds in an underwritten public offering of its common stock. In July 2021, the Company raised approximately $108 million in net proceeds in an underwritten public offering of its common stock.

Fourth Quarter and Year Ended 2021 Operational Update and 2022 Cash Guidance

- As of December 31, 2021, the Company had approximately $381.7 million in cash, cash equivalents and marketable securities.

- The Company estimates its year-end 2022 cash, cash equivalents and marketable securities will range between $215 million 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 a 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.

2021 Q4 Financial Highlights

- **R&D Expenses**: Research and development expenses were $25.1 million for the quarter ended December 31, 2021, compared to $17.5 million for the same period in 2020. For the year ended December 31, 2021, research and development expenses were $85.1 million compared to $62.8 million for the same period in 2020. Research and development expenses increased year over year primarily due to the commencement and completion of patient enrollment for the GATHER2 clinical trial, increased manufacturing activities for Zimura and increases in personnel costs, including

share-based compensation associated with additional research and development staffing. This increase in costs was partially offset by decreases in costs associated with the Company's gene therapy programs.

- **G&A Expenses**: General and administrative expenses were $8.0 million for the quarter ended December 31, 2021 and for the same period in 2020. For the year ended December 31, 2021, general and administration expenses were $29.7 million, compared to $26.0 million for the same period in 2020. General and administration expenses increased year over year primarily due to an increase in external costs, including legal and consulting costs associated with litigation, pre-commercialization activities and other administrative costs necessary to support the Company's operations.

- **Income Tax Benefit**: The Company recorded no income tax benefit for the three months ended December 31, 2021 and 2020 and the year ended December 31, 2021. Income tax benefit of $3.7 million for the year ended December 31, 2020, was recognized to reflect a favorable settlement of a state corporate income tax audit.

- **Net Loss**: The Company reported a net loss for the quarter ended December 31, 2021 of $33.0 million, or ($0.29) per diluted share, compared to a net loss of $25.4 million, or $(0.27) per diluted share, for the same period in 2020. For the year ended December 31, 2021, the Company reported a net loss of $114.5 million or ($1.12) per diluted share, compared to a net loss of $84.5 million or ($1.14) for the same period in 2020.

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 February 24, 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 8865993. 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 8000837.

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 retina 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 Phase 3 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, 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 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 mechanism of action and 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 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 December 31,		Year Ended December 31,	
	2021	2020	2021	2020
Statements of Operations Data:				

Operating expenses:				
Research and development	$ 25,096	$ 17,473	$ 85,068	$ 62,784
General and administrative	8,001	8,022	29,689	25,952
Total operating expenses	33,097	25,495	114,757	88,736
Loss from operations	(33,097)	(25,495)	(114,757)	(88,736)
Interest income	61	63	245	500
Other income (expense), net	3	-	(10)	(6)
Loss before income tax benefit	(33,033)	(25,432)	(114,522)	(88,242)
Income tax benefit	-	-	-	3,695
Net loss	$ (33,033)	$ (25,432)	$ (114,522)	$ (84,547)
Net loss per common share:				
Basic and diluted	$ (0.29)	$ (0.27)	$ (1.12)	$ (1.14)
Weighted average common shares outstanding:				
Basic and diluted	115,073	92,810	101,866	74,185

	December 31, 2021	December 31, 2020
	(in thousands)	
Balance Sheets Data:		
Cash, cash equivalents and marketable securities	$ 381,749	$ 210,047
Total assets	$ 389,358	$ 216,754
Total liabilities	$ 28,830	$ 25,191
Additional paid-in capital	$ 1,040,098	$ 756,543
Accumulated deficit	$ (679,595)	$ (565,073)
Total stockholders' equity	$ 360,528	$ 191,563

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Investor Contact:
Iveric Bio
Kathy Galante
Senior Vice President, Investor Relations
kathy.galante@ivericbio.com
212-845-8231

or

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

Source: IVERIC bio, Inc.