Iveric Bio Reports First Quarter 2021 Operational Highlights and Financial Results

May 5, 2021

- GATHER2 On-Track to Complete Enrollment in 3Q of this Year -

- Conference Call and Webcast Today, May 5, 2021, at 8:00 a.m. ET -

NEW YORK--(BUSINESS WIRE)--May 5, 2021-- IVERIC bio, Inc. (Nasdaq: ISEE) today announced financial and operating results for the quarter ended March 31, 2021 and provided a general business update.

"Iveric Bio is entering an important period as we remain focused on the execution of our ongoing Zimura GATHER2 clinical trial, which is our second Phase 3 clinical trial for Zimura for the treatment of geographic atrophy secondary to age-related macular degeneration. We are committed to completing recruitment for the GATHER2 trial in the third quarter of this year," stated Glenn P. Sblendorio, Chief Executive Officer of Iveric Bio. "To date, both the recruitment and retention of patients in GATHER2 have exceeded our expectations. We are on track for initial, topline data from GATHER2 to be available approximately one year after the recruitment of the last patient in the GATHER2 clinical trial, plus the time needed for database closure and analysis of the initial, topline data."

"A key goal of ours is to expand and advance our footprint in multiple stages and types of AMD," stated Pravin U. Dugel, M.D., President of Iveric Bio. "We are excited by the opportunity to potentially expand the reach of Zimura beyond GA and to continue the development of IC-500, our HtrA1 inhibitor, which we expect could be complementary to Zimura in treating AMD patients. We remain committed to developing safe and effective therapeutic and gene therapy treatment options for retinal diseases with significant unmet medical needs."

Therapeutics Programs Targeting Geographic Atrophy Secondary to Age-Related Macular Degeneration

Zimura® (avacincaptad pegol): Complement C5 Inhibitor

- Enrollment and retention for GATHER2, the Company's pivotal clinical trial of Zimura in development for the treatment of geographic atrophy (GA) secondary to age-related macular degeneration (AMD), are progressing well with enrollment on target. In March 2021, the Company announced it accelerated the timeline for when it expects to complete enrollment in GATHER2 to the third quarter of 2021.

- The Phase 2b screening clinical trial of Zimura for the treatment of autosomal recessive Stargardt disease, referred to as the STAR trial, is ongoing with the goal of enrolling approximately 120 patients.

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

- During the first quarter of 2021, the Company revised its development plans for IC-500 to include plans to investigate multiple dosing schedules for this product candidate. In April 2021, the Company commenced its first preclinical tolerability study for IC-500 and is currently planning additional preclinical studies, including pharmacokinetic and target engagement studies. Formulation optimization and other manufacturing activities are also ongoing. The Company expects to submit an IND to the FDA for IC-500 in GA secondary to AMD in the second half of 2022.

Iveric Bio to Host Dry AMD Virtual Symposium for Investors/Analysts

The Company will host a dry AMD Virtual Symposium for investors and analysts on Friday, June 18, 2021 from 10:00am – 12:00pm Eastern Time. The event will include presentations and discussions with retinal specialists and key opinion leaders on the dry AMD landscape, Zimura pivotal program in GA and highlights from the Company's IC-500 program in AMD. 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.

Gene Therapy Programs in Orphan Inherited Retinal Diseases (IRDs)

- ***IC-200: BEST1-Related IRDs***
  The Company is completing a preclinical efficacy and toxicology study for IC-200, in the naturally occurring canine model of Best disease. Published data have demonstrated long-term rescue in this model following a single sub-retinal injection. The Company is on track to release the recently manufactured cGMP batch of IC-200 in preparation for the planned IND filing and plans to move IC-200 into the clinic, in a Phase 1/2 trial in the second half of 2021.

- ***IC-100: Rhodopsin-Mediated Autosomal Dominant Retinitis Pigmentosa (RHO-adRP)***.
  The Company continues to evaluate the results of preclinical toxicology studies for IC-100. In the Company's preclinical efficacy and toxicology study in a naturally occurring canine model of RHO-adRP, efficacy was demonstrated at all three

doses tested. The Company also tested the same three doses in a GLP toxicology study in non-human primates. Ocular inflammation on clinical exam was observed in the high dose group in canines and to varying degrees at different dosing levels tested in non-human primates. Due to the different findings in the two different species, and the Company's high commitment to the safety of its patients, the Company is planning to discuss with regulators the design of its planned first-in-human clinical trial for IC-100 prior to submitting an IND. The Company now believes that IC-100 will likely be delayed from entering into a Phase 1/2 clinical trial this year.

- ***Minigene Programs***
  The Company, in its minigene collaboration with the University of Massachusetts Medical School, has identified a lead construct for its Leber Congenital Amaurosis Type 10 (LCA10) program and is currently considering development plans for this program. The Company expects to obtain additional results from its Stargardt Disease (ABCA4) program in the second quarter of 2021, and expects to obtain preliminary results from its USH2A-related inherited retinal diseases program in the second half of 2021.

The Company announced today the formation of its Gene Therapy Inherited Retina Disease Scientific Advisory Committee that will work closely with senior management as the Company advances its gene therapy inherited retinal disease programs. The members of the advisory committee include:

- Elias Traboulsi, MD, MEd
  Head of the Department of Pediatric Ophthalmology
  Director of the Center for Genetic Eye Diseases
  Cole Eye Institute
  Professor of Ophthalmology, Cleveland Clinic Lerner College of Medicine,
  Cleveland Clinic

- Andreas K. Lauer, MD
  Chair, Department of Ophthalmology, Casey Eye Institute
  Professor of Ophthalmology, School of Medicine

- Bart P. Leroy, MD, PhD
  Head, Department of Ophthalmology, Ghent University Hospital
  Senior Staff Member, Center for Medical Genetics Ghent, Ghent University Hospital
  Professor of Ophthalmology & Ophthalmic Genetics, Ghent University
  Director of the Retinal Degenerations Clinic Children's Hospital of Philadelphia

- Mark Pennesi, MD, PhD
  Division Chief, Ophthalmic Genetics
  Associate Professor in Ophthalmology, Oregon Health & Science University

- Eleonora Lad, MD, PhD
  Director of Grading, Duke Reading Center
  Associate Professor of Ophthalmology, Duke University Medical Center

Board of Directors and Management

- Today the Company announced the promotions of Pravin U. Dugel, MD, to President, and Kathy Galante to Senior Vice President, Investor Relations, both effective as of May 1.

- In April 2021, the Company announced that David R. Guyer, MD, was stepping down from the Iveric Bio Board of Directors after 14 years, effective following Iveric Bio's 2021 Annual Stockholder Meeting scheduled to be held on May 19, 2021.

First Quarter Financial Results and 2021 Cash Guidance

- As of March 31, 2021, the Company had $180.2 million in cash, cash equivalents and available for sale securities.

- The Company estimates its year-end 2021 cash, cash equivalents and available for sale securities to range between $125 and $135 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, excluding any potential approval or sales milestones payable to Archemix Corp. or any commercialization expenses for Zimura, into 2024. These estimates are based on the Company's current business plan, including the continuation of its ongoing clinical development programs for Zimura, the progression of its IC-100 and IC-200 programs into the clinic, and the advancement of its IC-500 development program. These estimates also assume that the Company will enroll approximately 400 patients in the GATHER2 trial. These estimates do not reflect any additional expenditures related to potentially studying Zimura in other indications or resulting from the potential in-licensing or acquisition of additional product candidates or technologies or commencement of

new sponsored research programs, and any associated development the Company may pursue.

2021 Q1 Financial Highlights

- **R&D Expenses**: Research and development expenses were $18.5 million for the quarter ended March 31, 2021, compared to $13.8 million for the same period in 2020. Research and development expenses increased primarily due to the initiation of our GATHER2 trial and commencement of patient enrollment and increased manufacturing activities for Zimura, increased manufacturing and preclinical development activities associated with the Company's IC-100 and IC-200 gene therapy programs and the progression of its IC-500 development program.

- **G&A Expenses**: General and administrative expenses were $8.3 million for the quarter ended March 31, 2021, compared to $5.0 million for the same period in 2020. General and administration expenses increased primarily due to legal costs associated with ongoing litigation.

- **Income Tax Benefit**: For the quarter ended March 31, 2021, the Company recorded no income tax benefit. An income tax benefit of $3.3 million was recognized in the quarter ended March 31, 2020 to reflect a favorable settlement of a state corporate income tax audit.

- **Net Loss**: The Company reported a net loss for the quarter ended March 31, 2021 of $26.8 million, or ($0.29) per diluted share, compared to a net loss of $15.1 million, or $(0.28) per diluted share, 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 May 5, 2021 at 8:00 a.m. Eastern Time. To participate in this conference call, dial 888-317-6003 (USA) or 412-317-6061 (International), passcode 5841649. 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 877-344-7529 (USA) or 412-317-0088, passcode 10153477.

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. 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 regarding patient enrollment and patient retention in its second Phase 3 trial (GATHER2) of Zimura in geographic atrophy secondary to AMD and use of the results from its completed clinical trial of Zimura for the treatment of geographic atrophy secondary to AMD (GATHER1) as a Phase 3 trial, its development and regulatory strategy for Zimura and its other product candidates, including additional indications that the Company may pursue for the development of Zimura and IC-500, the implementation of its business plan, its expectations regarding expected cash, cash equivalents and available for sale securities and the sufficiency of its cash resources, the timing, progress and results of clinical trials and other research and development activities and regulatory submissions, the potential utility of its product candidates, the potential for its business development strategy and its personnel, advisory committee members 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, the initiation and the progress of research and development programs and clinical trials, including enrollment and retention in clinical trials, availability of data from these programs, reliance on contract development and manufacturing organizations, university collaborators and other third parties, establishment of manufacturing capabilities, expectations for regulatory matters, developments from the Company's competitors and the marketplace for the Company's products, 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.

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

	Three Months Ended March 31,	
	2021	**2020**

Statements of Operations Data:

Operating expenses:		
Research and development	$ 18,549	$ 13,750
General and administrative	8,322	4,998
Total operating expenses	26,871	18,748
Loss from operations	(26,871)	(18,748)
Interest income	77	358
Other income (expense), net	(1)	5
Loss before income benefit	(26,795)	(18,385)
Income tax benefit	-	3,309
Net loss	$ (26,795)	$ (15,076)
Net loss per common share:		
Basic and diluted	$ (0.29)	$ (0.28)
Weighted average common shares outstanding:		
Basic and diluted	93,311	53,426

	March 31, 2021	December 31, 2020
	(in thousands)	
Balance Sheets Data:		
Cash, cash equivalents and marketable securities	$ 180,201	$ 210,047
Total assets	$ 187,402	$ 216,754
Total liabilities	$ 20,214	$ 25,191
Additional paid-in capital	$ 758,964	$ 756,543
Accumulated deficit	$ (591,868)	$ (565,073)
Total stockholders' equity	$ 167,188	$ 191,563

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