IVERIC bio Reports Second Quarter 2020 Operational Highlights and Financial Results

August 5, 2020

- Conference Call and Webcast Today, August 5, 2020, at 8:00 a.m. ET -

NEW YORK--(BUSINESS WIRE)--Aug. 5, 2020-- IVERIC bio, Inc. (Nasdaq: ISEE) today announced financial and operating results for the fiscal quarter ended June 30, 2020 and provided a general business update.

“Following the positive results from our GATHER1 Phase 3 clinical trial of Zimura for the treatment of geographic atrophy secondary to age-related macular degeneration, our main priority is to aggressively drive patient recruitment and retention in GATHER2, our second Phase 3 clinical trial for the treatment of GA secondary to AMD,” stated Glenn P. Sblendorio, Chief Executive Officer and President of IVERIC bio. “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. The enthusiasm, resiliency and dedication of patients, physicians and their staffs fueled by their confidence in the GATHER1 Phase 3 results are exceeding our expectations.”

Mr. Sblendorio added, “During the second quarter, we strengthened our balance sheet with a public offering and a concurrent private placement. We believe this enables us to further execute on our strategy to develop and deliver retinal treatments through our Zimura, gene therapy and HtrA1 inhibitor programs, with the potential to create long-term shareholder value.”

Age-Related Macular Degeneration Programs

Zimura® (avacincaptad pegol): Complement C5 Inhibitor

- In June 2020, the Company announced positive 18 month results from GATHER1, its first Phase 3 clinical trial for Zimura, a novel complement C5 inhibitor, for the treatment of geographic atrophy (GA) secondary to age-related macular degeneration (AMD). The 18 month data supports the previously announced 12 month data from this trial, at which time point Zimura met the pre-specified primary efficacy endpoint with statistical significance. Zimura was generally well tolerated after 18 months of administration.
- The GATHER1 data was presented at The Association for Research in Vision and Ophthalmology (ARVO) Annual Meeting, May 3 – 7, 2020 by Karl G. Csaky, MD, T. Boone Pickens Senior Scientist and Director of the Molecular Ophthalmology Laboratory at the Retina Foundation of the Southwest, and was also presented at the American Society of Retina Specialists (ASRS) Annual Scientific Meeting, July 24 – 26, 2020 by Baruch D. Kuppermann, MD, Chairman of the Department of Ophthalmology at UC Irvine.
- In late June 2020, the Company announced that the first patient had been dosed in GATHER2, its second Phase 3 clinical trial for Zimura in development for the treatment of GA secondary to AMD. If 12 month results from GATHER2 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.
- In April 2020, the U.S. FDA granted Fast Track designation for Zimura for the treatment of GA secondary to AMD. Fast Track designation offers important benefits, including frequent interactions with the FDA and the potential eligibility for rolling submission and priority review of a New Drug Application, if relevant criteria are met.
- The Company increased the enrollment target in its ongoing Phase 2b screening clinical trial of Zimura for the treatment of autosomal recessive Stargardt disease. After initially enrolling 95 patients in this trial, the Company plans to enroll approximately 25 additional patients, with the goal of enrolling a total of 120 patients as was initially intended in the protocol for this trial.

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

- The Company selected a lead product candidate from its HtrA1 inhibitor program, which it will refer to as IC-500. Based on current timelines, the Company is planning to submit an IND with the U.S. FDA for IC-500 in GA secondary to AMD in 2021.

Gene Therapy Programs in Orphan Inherited Retinal Diseases (IRDs)

- ***IC-100: Rhodopsin-Mediated Autosomal Dominant Retinitis Pigmentosa (RHO-adRP) and IC-200: BEST1-Related IRDs***
  Natural history studies and IND-enabling activities for IC-100 and IC-200 are ongoing. The Company plans to begin enrolling patients in Phase 1/2 clinical trials for IC-100 during the first half of 2021 and for IC-200 in 2021.
- ***Minigene Programs***

The Company, in collaboration with the University of Massachusetts Medical School, continues to advance its minigene program for Leber Congenital Amaurosis Type 10 (LCA10), autosomal recessive Stargardt Disease (ABCA4), and USH2A-related IRDs. The Company expects to select a lead construct for its LCA10 minigene program and obtain additional results for its Stargardt Disease minigene program by the end of 2020. The Company expects to obtain preliminary results from its USH2A minigene program in late 2020 or early 2021.

Corporate Update
In April 2020, the Company appointed Pravin U. Dugel, MD as Executive Vice President and Chief Strategy and Business Officer. In July 2020, Mark S. Blumenkranz, MD, MMS, joined its board of directors.

Second Quarter 2020 Operational Update and Cash Guidance
As of June 30, 2020, the Company had $245.7 million in cash and cash equivalents. In June 2020, the Company raised approximately $150 million in net proceeds in an underwritten public offering of common stock, and pre-funded warrants in lieu of common stock, and a concurrent private placement of common stock. The Company now estimates that its year-end 2020 cash and cash equivalents will range between $215 million and $220 million. The Company also estimates that its cash and cash equivalents will be sufficient to fund its currently planned capital expenditure requirements and operating expenses, excluding any potential approval or sales milestones payable to Archemix Corp. or any commercialization expenses for Zimura, through at least mid-2024. These estimates are based on the Company's current business plan, which includes the continuation of the Company's clinical development programs for Zimura, the progression of the Company's IC-100 and IC-200 programs into the clinic, and the advancement of the Company's IC-500 development program. These estimates assume that the Company will enroll approximately 400 patients in the GATHER2 trial. These estimates do not reflect any additional expenditures resulting from the potential in-licensing or acquisition of additional product candidates or technologies, commencement of any new sponsored research programs, or any associated develop that the Company may pursue.

2020 Q2 Financial Highlights

- **R&D Expenses**: Research and development expenses were $12.7 million for the quarter ended June 30, 2020, compared to $10.0 million for the same period in 2019. For the six months ended June 30, 2020, research and development expenses were $26.5 million compared to $17.7 million for the same period in 2019. Research and development expenses increased primarily due to increased manufacturing and preclinical development costs associated with the Company's IC-100 and IC-200 gene therapy programs, the initiation and start-up activities for its GATHER2 clinical trial, manufacturing activities for Zimura and the progression of its HtrA1 inhibitor program.
- **G&A Expenses**: General and administrative expenses were $6.3 million for the quarter ended June 30, 2020, compared to $5.2 million for the same period in 2019. For the six months ended June 30, 2020, general and administrative expenses were $11.3 million compared to $10.7 million for the same period in 2019. General and administration expenses increased primarily due to increases in professional fees and general consulting costs.
- **Income Tax (Benefit):** Income tax benefits of $0.4 million and $3.7 million for the three and six months ended June 30, 2020, respectively, were recognized to reflect a favorable settlement of a state corporate income tax audit.
- **Net Income**: The Company reported a net loss for the quarter ended June 30, 2020 of $18.6 million, or ($0.32) per diluted share, compared to a net loss of $14.4 million, or ($0.35) per diluted share, for the same period in 2019. For the six months ended June 30, 2020, the Company reported a net loss of $33.7 million or ($0.61) per diluted share, compared to a net loss of $26.9 million or ($0.65) for the same period in 2019.

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 August 5, 2020 at 8:00 a.m. Eastern Time. To participate in this conference call, dial 888-220-8451 (USA) or 323-794-2588 (International), passcode 2738321. 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 888-203-1112 (USA), passcode 2738321.

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 the impact of the COVID-19 pandemic on the Company's research and development programs, operations and financial position, its expectations regarding patient enrollment and patient retention in its second Phase 3 trial (GATHER2) of Zimura in geographic atrophy secondary to AMD and to use the results of its completed clinical trial of Zimura for the treatment of geographic atrophy secondary to AMD (GATHER1) as a Phase 3 trial, expectations regarding patient enrollment and patient retention in its Phase 2b screening trial of Zimura for autosomal recessive Stargardt disease, its development and regulatory strategy for Zimura and its other product candidates, the implementation of its business plan, the projected use of cash and cash balances, the timing, progress and results of clinical trials and other research and development activities and regulatory submissions, the potential utility of its product candidates, 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 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 contract development and manufacturing organizations, 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.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	**2019**	**2020**	**2019**
Statements of Operations Data:				
Operating expenses:				
Research and development	$ 12,720	$ 10,009	$ 26,470	$ 17,694
General and administrative	6,289	5,198	11,287	10,679
Total operating expenses	19,009	15,207	37,757	28,373
Loss from operations	(19,009)	(15,207)	(37,757)	(28,373)
Interest income	46	617	404	1,287
Other income (expense)	(12)	151	(7)	151
Loss before income tax provision (benefit)	(18,975)	(14,439)	(37,360)	(26,935)
Income tax provision (benefit)	(386)	4	(3,695)	9
Net loss	$ (18,589)	$ (14,443)	$ (33,665)	$ (26,944)
Net loss per common share:				
Basic and diluted	$ (0.32)	$ (0.35)	$ (0.61)	$ (0.65)
Weighted average common shares outstanding:				
Basic and diluted	$ 57,421	$ 41,477	$ 55,424	$ 41,452

	June 30, 2020	**December 31, 2019**
	(in thousands)	
Balance Sheets Data:		
Cash and cash equivalents	$ 245,735	$ 125,699
Total assets	$ 249,950	$ 130,187
Total liabilities	$ 11,909	$ 12,984
Additional paid-in capital	$ 752,143	$ 597,679
Accumulated deficit	$ (514,191)	$ (480,526)

Total stockholders' equity	$ 238,041	$ 117,203

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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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