Iveric Bio Reports Third Quarter 2020 Operational Highlights and Financial Results

November 2, 2020

- Conference Call and Webcast Today, November 2, 2020, at 8:00 a.m. ET -

NEW YORK--(BUSINESS WIRE)--Nov. 2, 2020-- IVERIC bio, Inc. (Nasdaq: ISEE) today announced financial and operating results for the fiscal quarter ended September 30, 2020 and provided a general business update.

"It has been a landmark year as we have achieved several major milestones for Zimura," stated Glenn P. Sblendorio, Chief Executive Officer and President of IVERIC bio. "Over the past year, we announced positive 12-month and 18-month results from our GATHER1 Phase 3 clinical trial of Zimura for the treatment of geographic atrophy secondary to age-related macular degeneration. We initiated patient enrollment in GATHER2, our second Phase 3 clinical trial for the treatment of GA secondary to AMD. Additionally, we strengthened our balance sheet, advanced our two lead gene therapy product candidates to be on track to enter into the clinic next year and identified a lead compound for our HtrA1 inhibitor program."

Pravin U. Dugel, M.D., Chief Strategy and Business Officer of IVERIC bio added, "We are excited about the momentum generated with Zimura as a potential treatment for GA and, based on scientific data, Zimura's potential impact in wet (neovascular) AMD and in earlier stages of dry AMD. We are also encouraged by our HtrA1 inhibitor, IC-500, which we believe could be another important target in the treatment of AMD. Looking forward, our goal is to expand our footprint in multiple stages and types of AMD, dry and wet. We intend to do this by potentially studying Zimura in additional indications and by advancing the development of IC-500. We expect to make great strides in 2021, as we continue to move our pipeline of therapeutics and gene therapy product candidates forward."

Therapeutics Programs Targeting Age-Related Macular Degeneration

- ***Zimura® (avacincaptad pegol): Complement C5 Inhibitor***
  In September 2020, the Company announced that the positive Phase 3 results from its GATHER1 clinical trial with Zimura were published in *Ophthalmology®*, the Journal of the American Academy of Ophthalmology. The published article is available online at https://www.aaojournal.org/article/S0161-6420(20)30845-9/fulltext.

- Today, the Company announced that the positive GATHER1 data from the first Zimura Phase 3 clinical trial will be presented at the 2020 American Academy of Ophthalmology - Retina Subspecialty Day Virtual Annual Meeting, November 13, 2020 at 6:10pm ET by Dr. Donald J. D'Amico, Professor and Chairman of Ophthalmology at Weill Cornell Medical College and Ophthalmologist-in-Chief at the New York Presbyterian Hospital.

The GATHER1 data were recently presented at the following virtual conferences:

  - Virtual EURETINA Annual Meeting, by Dr. Frank G. Holz, Professor and Chair of the Department of Ophthalmology, University of Bonn, Germany;
  - Retina Society Annual Meeting, by Dr. Carl D. Regillo, Chief, Retina Services at Wills Eye Hospital;
  - Meeting of the Club Jules Gonin, by Dr. Glenn J. Jaffe, Robert Machemer Professor of Ophthalmology and a member of the Vitreoretinal Faculty at Duke University Eye; and
  - American Society of Retina Specialists Annual Meeting, by Dr. Baruch D. Kuppermann, 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 for the treatment of GA secondary to AMD. If 12-month results from GATHER2 are positive, the Company plans to file applications with the U.S. Food and Drug Administration and the European Medicines Agency for marketing approval of Zimura for GA.

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

- 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 to the FDA for IC-500 in GA secondary to AMD in the second half of 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***

IND-enabling activities for IC-100 and IC-200, and natural history studies for IC-200, are ongoing. The Company plans to file an IND for IC-100 with the FDA in early 2021 and begin enrolling patients in a Phase 1/2 clinical trial for IC-100 during the first half of 2021. The Company plans to file an IND for IC-200 with the FDA in the middle of 2021 and begin enrolling patients in a Phase 1/2 clinical trial for IC-200 in the second half of 2021.

- ***Minigene Programs***
  The Company, in collaboration with the University of Massachusetts Medical School, continues to advance its minigene programs 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 in the fourth quarter of 2020 or early 2021. The Company expects to obtain additional results from its Stargardt Disease minigene program in early 2021. The Company expects to obtain preliminary results from its USH2A minigene program in early 2021.

Corporate Update

In July 2020, Mark S. Blumenkranz, M.D., M.M.S., joined the Company's board of directors. Dr. Blumenkranz is a biotechnology industry leader and internationally known Vitreo-Retinal Specialist with notable expertise in pharmaceuticals for age-related macular degeneration and ocular gene therapy.

Third Quarter 2020 Operational Update and Cash Guidance

As of September 30, 2020, the Company had $231.1 million in cash, cash equivalents and available for sale securities. The Company has revised its estimated year-end 2020 cash, cash equivalents and available for sale securities to range between $210 million and $215 million, reflecting the impact of a fourth quarter $6.0 million milestone payment to Archemix Corp. 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, 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, 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.

2020 Q3 Financial Highlights

- **R&D Expenses**: Research and development expenses were $18.8 million for the quarter ended September 30, 2020, compared to $10.4 million for the same period in 2019. For the nine months ended September 30, 2020, research and development expenses were $45.3 million compared to $28.1 million for the same period in 2019. Research and development expenses increased primarily due to increased manufacturing and preclinical development activities associated with the Company's IC-100 and IC-200 gene therapy programs, the completion of its GATHER1 clinical trial, the initiation of its GATHER2 clinical trial and the progression of its IC-500 development program.

- **G&A Expenses**: General and administrative expenses were $6.6 million for the quarter ended September 30, 2020, compared to $4.7 million for the same period in 2019. For the nine months ended September 30, 2020, general and administrative expenses were $17.9 million compared to $15.4 million for the same period in 2019. General and administration expenses increased primarily due to increases in general consulting costs and professional fees.

- **Net Income**: The Company reported a net loss for the quarter ended September 30, 2020 of $25.5 million, or ($0.27) per diluted share, compared to net loss of $14.4 million, or ($0.35) per diluted share, for the same period in 2019. For the nine months ended September 30, 2020, the Company reported a net loss of $59.1 million or ($0.87) per diluted share, compared to a net loss of $41.4 million or ($1.00) 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 November 2, 2020 at 8:00 a.m. Eastern Time. To participate in this conference call, dial 866-575-6539 (USA) or 323-794-2575 (International), passcode 6339331. 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 6339331.

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.

Website Disclaimer

We have included website addresses in this press release solely as inactive references. The information contained on, or that can be accessed

through, such websites is not a part of this press release.

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 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, 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, 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, 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 September 30,		Nine Months Ended September 30,	
	2020	**2019**	**2020**	**2019**
Statements of Operations Data:				
Operating expenses:				
Research and development	$ 18,841	$ 10,383	$ 45,311	$ 28,077
General and administrative	6,643	4,674	17,930	15,353
Total operating expenses	25,484	15,057	63,241	43,430
Loss from operations	(25,484)	(15,057)	(63,241)	(43,430)
Interest income	33	495	437	1,782
Other income (expense)	1	-	(6)	151
Loss before income tax benefit	(25,450)	(14,562)	(62,810)	(41,497)
Income tax benefit	-	(125)	(3,695)	(116)
Net loss	$ (25,450)	$ (14,437)	$ (59,115)	$ (41,381)
Net loss per common share:				
Basic and diluted	$ (0.27)	$ (0.35)	$ (0.87)	$ (1.00)
Weighted average common shares outstanding:				
Basic and diluted	$ 92,675	$ 41,552	$ 67,931	$ 41,486

	September 30, 2020	December 31, 2019
	(in thousands)	
Balance Sheets Data:		
Cash, cash equivalents and marketable securities	$ 231,122	$ 125,699
Total assets	$ 234,595	$ 130,187
Total liabilities	$ 20,009	$ 12,984
Additional paid-in capital	$ 754,136	$ 597,679
Accumulated deficit	$ (539,641)	$ (480,526)
Total stockholders' equity	$ 214,586	$ 117,203

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