Iveric Bio Reports First Quarter 2020 Operational Highlights and Financial Results

May 6, 2020

- Conference Call and Webcast Today, May 6, 2020, at 8:00 a.m. ET -

NEW YORK--(BUSINESS WIRE)--May 6, 2020--

IVERIC bio, Inc. (Nasdaq: ISEE) today announced financial and operating results for the fiscal quarter ended March 31, 2020 and provided a general business update.

“From the onset of this terrible coronavirus (COVID-19) pandemic, our main priority has been the health and safety of patients and their caregivers, physicians and their staffs, and our employees and collaborators,” stated Glenn P. Sblendorio, Chief Executive Officer and President of IVERIC bio. “The first quarter brought unprecedented times, so we chose to pause the initiation of patient enrollment in our second Phase 3 clinical trial of Zimura for the treatment of geographic atrophy secondary to age-related macular degeneration. Due to the dedication and unwavering support of our clinical investigators and their staffs along with our experienced clinical operations team, we put into place an aggressive strategy for Zimura and continue to activate additional sites and progress other trial startup activities, including identification of potential patients, so that we can be in a position to expeditiously begin enrolling patients as soon as we determine the appropriate time to do so. We are excited that Zimura has received Fast Track designation from the U.S. FDA.”

Mr. Sblendorio added, “Following the positive efficacy results and favorable safety profile observed in our initial Phase 3 clinical trial of Zimura and along with advancing our inherited retinal disease gene therapy programs, now is the ideal time to welcome Dr. Pravin Dugel to our executive management team. Pravin brings an extensive network and long-standing relationships with the retinal medical community and the biotech/pharma ophthalmic industry. He will help lead the Company’s strategy and build alliances with potential collaborators, investors and other stakeholders.”

Zimura® (avacincaptad pegol): Complement C5 Inhibitor

- In January 2020, the Company announced the design of its second Phase 3 clinical trial of Zimura in geographic atrophy secondary to AMD, ISEE2008. The Company plans to enroll approximately 400 patients in this international, multicenter, double masked, sham controlled clinical trial. Patients will be randomized to receive either monthly administration of Zimura 2mg or sham during the first 12 months of the trial, at which time the primary efficacy analysis of the mean rate of change of GA growth over 12 months will be performed. If the primary efficacy endpoint is met at month 12, 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. At month 12, the Company plans to re-randomize patients in the Zimura 2 mg arm to receive either monthly or every other month administration of Zimura 2 mg. Patients who were initially randomized to the sham control arm will continue with monthly administration of sham. The final evaluation will take place at month 24.

- On March 18, 2020, the Company announced that due to the COVID-19 pandemic, it had decided to delay the initiation of patient enrollment in the ISEE2008 trial, which was otherwise on track to begin in March 2020. The Company continues to monitor the situation closely in the United States and abroad to determine when enrollment should begin.

- 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 expects topline 18-month data from its first Phase 3 clinical trial evaluating Zimura for the treatment of GA secondary to AMD, OPH2003, will be available by the end of the second quarter of 2020. The primary purpose of the 18-month timepoint is to gather additional safety data.

- The Company’s ongoing Phase 2b screening clinical trial of Zimura for the treatment of autosomal recessive Stargardt disease, an orphan inherited retinal disease, is on track for top-line data to be available during the second half of 2020.

Gene Therapy Programs in Orphan Inherited Retinal Diseases (IRDs)

- ***IC-100: Rhodopsin-Mediated Autosomal Dominant Retinitis Pigmentosa (RHO-adRP)***

  Natural history studies and IND-enabling activities for IC-100 are ongoing. The Company plans to file an IND for IC-100 by the end of 2020 or early 2021 and to begin enrolling patients in a Phase 1/2 clinical trial during the first half of 2021.

- ***IC-200: BEST1-Related IRDs***

Natural history studies and IND-enabling activities for IC-200 are ongoing. The Company plans to initiate a Phase 1/2 clinical trial for IC-200 during the first half of 2021.

- ***miniCEP290: Leber Congenital Amaurosis Type 10 (LCA10)***

IVERIC bio, in collaboration with the University of Massachusetts Medical School (UMass Medical School), is continuing to optimize the minigene constructs for this program with the goal of identifying a lead construct during the second half of 2020.

- ***miniABCA4 Program for Stargardt Disease (STGD1)***

IVERIC bio, through its collaborative sponsored research agreement with UMass Medical School, is evaluating several ABCA4 minigene constructs in both in vitro and in vivo experiments. The Company has received preliminary results and expects to receive additional results for the miniABCA4 program during the second half of 2020.

- ***miniUSH2A: USH2A-Related IRDs Including Usher Syndrome Type 2A (Usher 2A) and USH2A-Associated Nonsyndromic Autosomal Recessive Retinitis Pigmentosa***

This research program targets IRDs associated with mutations in the USH2A gene, including Usher 2A and USH2A-associated nonsyndromic autosomal recessive retinitis pigmentosa. The Company expects to receive preliminary results by late 2020.

Corporate Update

On April 1, 2020, IVERIC bio appointed Pravin U. Dugel, MD as Executive Vice President and Chief Strategy and Business Officer. Dr. Dugel reports to Glenn Sblendorio.

First Quarter Financial Results and 2020 Cash Guidance

As of March 31, 2020, the Company had $108.4 million in cash and cash equivalents. The Company now estimates that its year-end 2020 cash and cash equivalents will range between $65 million and $70 million. The Company also estimates that its cash and cash equivalents will be sufficient to fund its operations and capital expenditure requirements as currently planned into the beginning of 2022. These estimates are based on the Company's current 2020 business plan, including the initiation of the Zimura ISEE2008 Phase 3 clinical trial and the continuation of the Company's other on-going research and development programs. This estimate does not reflect any additional expenditures, including associated development costs, in the event the Company in-licenses or acquires any new product candidates or commences any new sponsored research programs.

2020 Q1 Financial Highlights

- **R&D Expenses**: Research and development expenses were $13.8 million for the quarter ended March 31, 2020, compared to $7.7 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 ISEE2008 clinical trial and progression of its HtrA1 inhibitor program.

- **G&A Expenses**: General and administrative expenses were $5.0 million for the quarter ended March 31, 2020, compared to $5.5 million for the same period in 2019. General and administrative expenses decreased primarily due to a decline in general consulting costs and professional fees.

- **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, 2020 of $15.1 million, or ($0.28) per diluted share, compared to a net loss of $12.5 million, or $(0.30) per diluted share, 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 May 6, 2020 at 8:00 a.m. Eastern Time. To participate in this conference call, dial 800-458-4148 (USA) or 323-794-2598 (International), passcode 6273033. 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 Toll Free), passcode 6273033.

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 to initiate enrollment in its second Phase 3 trial (ISEE2008) of Zimura in geographic atrophy secondary to AMD and to use its previously announced clinical trial of Zimura for the treatment of geographic atrophy (OPH2003) as a Phase 3 trial, its development and regulatory strategy for Zimura, 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, 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 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.

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

	Three Months Ended March 31,	
	2020	**2019**
Statements of Operations Data:		
Operating expenses:		
Research and development	$ 13,750	$ 7,685
General and administrative	4,998	5,481
Total operating expenses	18,748	13,166
Loss from operations	(18,748)	(13,166)
Interest income	358	670
Other income	5	-
Loss before income tax provision (benefit)	(18,385)	(12,496)
Income tax provision (benefit)	(3,309)	5
Net Income (loss)	$ (15,076)	$ (12,501)
Net loss per common share:		
Basic and diluted	$ (0.28)	$ (0.30)
Weighted average common shares outstanding:		
Basic and diluted	$ 53,426	$ 41,427

	March 31, 2020	**December 31, 2019**
	(in thousands)	
Balance Sheets Data:		
Cash and cash equivalents	$ 108,352	$ 125,699
Total assets	$ 115,714	$ 130,187
Total liabilities	$ 11,084	$ 12,984
Additional paid-in capital	$ 600,182	$ 597,679
Accumulated deficit	$ (495,602)	$ (480,526)
Total stockholders' equity	$ 104,630	$ 117,203

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