Iveric Bio Reports Third Quarter 2019 Operational Highlights and Financial Results

November 12, 2019

- Conference Call and Webcast Today, November 12, 2019, at 8:00 a.m. ET -

NEW YORK--(BUSINESS WIRE)--Nov. 12, 2019-- IVERIC bio, Inc. (Nasdaq: ISEE) today provided further details of the recently announced clinical trial results for the Company's Zimura ®(avacincaptad pegol) program in geographic atrophy (GA) secondary to dry age-related macular degeneration (AMD), reviewed the Company's financial results for the third quarter 2019 and provided a general business update.

Zimura® (avacincaptad pegol) Highlights

On October 28, 2019, IVERIC bio provided topline data confirming that Zimura® (avacincaptad pegol), the Company's complement factor C5 inhibitor, met its prespecified primary endpoint in reducing the mean rate of geographic atrophy (GA) growth in patients with dry age-related macular degeneration (AMD). Today, the Company provided further clinical details and the development strategy for Zimura in GA secondary to AMD. These announcements will be discussed during today's conference call/webcast (also see the second press release issued earlier today and the press release issued on October 28, 2019.)

"We are excited to have achieved a major milestone with our recent Zimura clinical trial results in geographic atrophy secondary to dry AMD and we look forward to start enrolling patients in a second pivotal clinical trial in the first quarter of 2020. We believe these events have the potential to be a catalyst for our company," stated Glenn P. Sblendorio, Chief Executive Officer and President of IVERIC bio. "IVERIC bio is now in a strong position, with a diversified, retina-focused portfolio, including both a late stage clinical program for a large market retinal disease and early stage gene therapy programs in inherited retinal diseases. We are committed to efficiently progressing these programs with the goal of continuing to create value for our shareholders."

Gene Therapy Highlights

Orphan IRD Gene Therapy Programs

- ***IC-100: Rhodopsin-Mediated Autosomal Dominant Retinitis Pigmentosa (RHO-adRP)***
  Natural history studies and IND-enabling activities for IC-100 are on track. The Company expects to initiate a Phase 1/2 clinical trial for IC-100 in patients with rhodopsin mediated adRP in the second half of 2020.
- ***IC-200: BEST1-Related IRDs***
  Natural history studies and IND-enabling activities for IC-200 are on track.
  The Company expects to initiate a Phase 1/2 clinical trial for IC-200 in patients with BEST1 related retinal diseases during the first half of 2021.
- ***miniCEP290: Leber Congenital Amaurosis Type 10 (LCA10)***
  Encouraging results from the Company's collaboration with the University of Massachusetts Medical School (UMass Medical School) in its miniCEP290 program led the Company to exercise its option and, in July 2019, the Company entered into an exclusive global license agreement with the University of Massachusetts for rights to develop and commercialize mutation independent novel AAV minigene therapy product candidates for the treatment of LCA10, which is due to mutations in the *CEP290* gene and is the most common type of LCA. The Company plans to provide an update on the lead minigene construct in early 2020.
- ***miniABCA4 Program for Stargardt Disease (STGD1)***
  The Company, 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 expects to have results from the miniABCA4 program in 2020.
- ***miniUSH2A: USH2A-Related IRDs Including Usher Syndrome Type 2A and USH2A-Associated Nonsyndromatic Autosomal Recessive Retinitis Pigmentosa***
  In July 2019, the Company entered into a sponsored research agreement with UMass Medical School and an exclusive option agreement with the University of Massachusetts for rights to develop and commercialize novel AAV gene therapy product candidates utilizing a mutation independent minigene therapy approach for the treatment of *USH2A*-related IRDs. This group of orphan IRDs include Usher syndrome Type 2A and *USH2A*-associated nonsyndromatic autosomal recessive retinitis pigmentosa.

On October 29, 2019, Abraham Scaria, PhD was appointed to the position of Chief Scientific Officer. Dr. Scaria will lead the Company's research and pre-clinical gene therapy activities. Dr. Scaria's extensive experience includes positions at Genzyme, Sanofi and most recently at Casebia Therapeutics, leading multiple ocular gene therapy programs.

Second Quarter 2019 Financial Results

Operational Update

As of September 30, 2019, the Company had $94.9 million in cash and cash equivalents. The Company reaffirms its estimate that year-end 2019 cash and cash equivalents will range between $80 million and $85 million. With the initiation of enrollment for the Company's second pivotal clinical trial for Zimura in GA planned for the first quarter of 2020, the Company estimates that its cash and cash equivalents will be sufficient to fund its operations and capital expenditure requirements as currently planned through the first half of 2021. These estimates are based on the Company's current business plan, including the continuation of its current research and development programs. This estimate does not reflect any additional expenditures in the event the Company were to in-license or acquire any new product candidates or commences any new sponsored research programs.

- **R&D Expenses**: Research and development expenses were $10.4 million for the quarter ended September 30, 2019, compared to $9.4 million for the same period in 2018. For the nine months ended September 30, 2019, research and development expenses were $28.1 million compared to $25.6 million for the same period in 2018. Research and development expenses increased primarily due to increases in costs associated with the Company's gene therapy programs and HtrA1 inhibitor program, offset by decreases in costs associated with the Company's Zimura programs.

- **G&A Expenses**: General and administrative expenses were $4.7 million for the quarter ended September 30, 2019, compared to $6.0 million for the same period in 2018. For the nine months ended September 30, 2019, general and administrative expenses were $15.4 million compared to $17.9 million for the same period in 2018. General and administrative expenses decreased primarily due to decreases in costs to support the Company's operations and infrastructure.

- **Net Income**: The Company reported a net loss for the quarter ended September 30, 2019 of $14.4 million, or ($0.35) per diluted share, compared to a net loss of $14.7 million, or ($0.41) per diluted share, for the same period in 2018. For the nine months ended September 30, 2019, the Company reported a net loss of $41.4 million or ($1.00) per diluted share, compared to a net loss of $41.0 million or ($1.13) for the same period in 2018.

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 12, 2019 at 8:00 a.m. Eastern Time. To participate in this conference call, dial 888-208-1711 (USA) or 323-994-2082 (International), passcode 5526863. 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 5526863.

About IVERIC bio

IVERIC bio is a biopharmaceutical company focused on the discovery and development of novel treatment options for retinal diseases with significant unmet medical needs. 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 to use its previously announced clinical trial of Zimura for the treatment of geographic atrophy as a pivotal trial, its development 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 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.

ISEE-G

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

Three Months Ended September 30,		Nine Months Ended September 30,	
2019	**2018**	**2019**	**2018**

Statements of Operations Data:

Operating expenses:				
Research and development	$ 10,383	$ 9,407	$ 28,077	$ 25,609
General and administrative	4,674	5,968	15,353	17,945
Total operating expenses	15,057	15,375	43,430	43,554
Loss from operations	(15,057)	(15,375)	(43,430)	(43,554)
Interest income	495	637	1,782	1,711
Other income (expense)	-	(1)	151	(17)
Loss before income tax provision (benefit)	(14,562)	(14,739)	(41,497)	(41,860)
Income tax provision (benefit)	(125)	6	(116)	(833)
Net loss	$ (14,437)	$ (14,745)	$ (41,381)	$ (41,027)
Net loss per common share:				
Basic and diluted	$ (0.35)	$ (0.41)	$ (1.00)	$ (1.13)
Weighted average common shares outstanding:				
Basic and diluted	41,552	36,202	41,486	36,181

	September 30, 2019	December 31, 2018
	(in thousands)	
Balance Sheets Data:		
Cash and cash equivalents	$ 94,851	$ 131,201
Total assets	98,823	137,165
Total liabilities	9,361	13,206
Additional paid-in capital	552,468	545,585
Accumulated deficit	(463,048)	(421,667)
Total stockholders' equity	$ 89,462	$ 123,959

View source version on businesswire.com: https://www.businesswire.com/news/home/20191112005571/en/

Source: IVERIC bio, Inc.

Investor:
IVERIC bio
Kathy Galante, 212-845-8231
Vice President, Investor Relations and Corporate Communications
kathy.galante@ivericbio.com

or

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