Iveric Bio Reports Third Quarter 2022 Operational Highlights and Financial Results

November 3, 2022

- Reported Positive GATHER2 Results for Avacincaptad Pegol in Geographic Atrophy -

- Planned NDA Submission Moved Up to End of This Year -

- Received Favorable Feedback from FDA on Intermediate AMD Development Plan -

- Conference Call and Webcast Today, November 3, 2022, at 8:00 a.m. ET -

PARSIPPANY, N.J.--(BUSINESS WIRE)--Nov. 3, 2022-- IVERIC bio, Inc. (Nasdaq: ISEE) today announced financial and operating results for the third quarter ended September 30, 2022 and provided a general business update.

"With the positive data from our GATHER2 clinical trial reported in the third quarter reinforcing the positive data from GATHER1, avacincaptad pegol (ACP) became the first and only investigational therapy in geographic atrophy (GA) to achieve its 12-month, prespecified, primary endpoint in two independent pivotal, Phase 3 clinical trials," stated Glenn P. Sblendorio, Chief Executive Officer of Iveric Bio. "We are excited to announce that we are ahead of schedule in preparing our new drug application (NDA) for ACP for the treatment of GA and we are moving up our submission timeline to the end of this year."

"As we close out the year and look forward to 2023, we are working diligently to make ACP available to physicians and their patients with GA as expeditiously as possible, subject to regulatory review and approval," stated Pravin U. Dugel, MD, President of Iveric Bio. "We continue to build our U.S. launch readiness plan and prepare for potential commercialization of ACP. We also continue to explore future development opportunities for ACP in earlier patient populations and to invest in lifecycle initiatives such as sustained release delivery technologies for ACP."

Avacincaptad pegol (ACP also known as Zimura): Complement C5 Inhibitor

- In September 2022, the Company announced that GATHER2, the Company's second Phase 3 clinical trial of ACP for the treatment of GA, met its pre-specified primary endpoint at 12 months with statistical significance and a favorable safety profile.
- Results from GATHER1, the Company's first Phase 3 clinical trial of ACP for the treatment of GA, and GATHER2, as well as the Company's Special Protocol Assessment with the U.S. Food and Drug Administration (FDA), provide the basis for an NDA, which the Company plans to submit to the FDA by the end of this year. The Company is also planning to submit a marketing authorization application (MAA) to the European Medicines Agency in 2023, subject to feedback from planned interactions with regulatory authorities in Europe.
- The GATHER2 topline results for ACP were presented in two oral sessions as part of the Retina Subspecialty Day at the American Academy of Ophthalmology 2022 Annual Meeting on September 30, 2022.
- The Company recently initiated an open-label extension (OLE) trial for patients who completed their month 24 visits in the GATHER2 trial, with the aim of providing patients access to ACP and collecting additional safety data. Patients will be treated with ACP for 18 months or until potential regulatory approval of ACP in the applicable region, whichever is earlier.
- The Company received favorable feedback from the FDA on its development plans for intermediate AMD. The Company is continuing to engage with the FDA regarding its development plans and strategy for this important patient population.
- In July 2022, a post-hoc analysis from the GATHER1 clinical trial was presented at the Annual Meeting of the American Society of Retina Specialists. In the post-hoc analysis, ACP was observed to be associated with a reduction in GA lesion growth compared to sham across all distances from the foveal center point.
- Patient enrollment in STAR, the Company's Phase 2b screening clinical trial of ACP for the treatment of autosomal recessive Stargardt disease (STGD1), is ongoing.

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

- The Company plans to conduct additional preclinical studies to optimize formulation, dosage and delivery of IC-500. As a result, the Company does not expect to submit an investigational new drug application for IC-500 mid-next year, as it had previously planned. The Company remains committed to this program and will provide additional information as it becomes

available.

Gene Therapy Programs in Orphan Inherited Retinal Diseases (IRDs)

- As the Company focuses its efforts and resources on the development and potential commercialization of ACP, the Company is currently seeking potential collaborators or licensees for the future development and potential commercialization of IC-100, the Company's product candidate for Rhodopsin-Mediated Autosomal Dominant Retinitis Pigmentosa (RHO-adRP) and IC-200, the Company's product candidate for BEST1-Related IRDs.
- The Company is continuing its minigene programs for Leber's Congenital Amaurosis type 10 (CEP290), autosomal recessive Stargardt Disease (ABCA4) and Usher's Syndrome (USH2A).

Non-Dilutive Debt Financing Facility

In July 2022, the Company entered into a term loan debt financing facility with Hercules Capital, Inc. (Hercules Capital) and Silicon Valley Bank (SVB) providing the Company with total borrowing capacity of up to $250 million in non-dilutive debt financing. In July 2022, the Company borrowed $50 million at the close of the facility. The Company believes it has satisfied the first performance milestone under that term loan facility, which would allow it to borrow an additional $50 million. The Company plans to borrow this additional amount in the fourth quarter of 2022.

Third Quarter Financial Results and 2022 Cash Guidance

- As of September 30, 2022, the Company had $321 million in cash, cash equivalents and available for sale securities, which reflects the impact of its $50 million initial borrowing under its term loan debt financing facility with Hercules and SVB.
- The Company estimates its year-end 2022 cash, cash equivalents and available for sale securities to range between $265 and $275 million. The Company estimates that its cash, cash equivalents, available for sale securities and committed loan facilities will be sufficient to fund its planned capital expenditure requirements, debt service obligations and operating expenses 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 ACP in GA and STGD1, including the recently initiated OLE trial, evaluating ACP for intermediate AMD, preparation and submission of an NDA and an MAA for ACP in GA, continuing preparations for potential commercialization of ACP in GA in the United States, pursuing DelSiTech's silica-based sustained release delivery technology and exploring additional sustained release delivery technologies for ACP, and the advancement of its IC-500 development program as currently planned. These estimates do not include any potential new borrowings under the term loan facility with Hercules and SVB, including the $50 million that the Company plans to borrow in the fourth quarter of this year. Also excluded from these estimates are any potential approval or sales milestones payable to Archemix Corp. or any potential expenses for actual commercial launch of ACP, such as associated sales force expenses, any additional expenditures related to potentially studying ACP in indications outside of GA, STGD1 and intermediate AMD, or resulting from the potential in-licensing or acquisition of additional product candidates or technologies, or any associated development the Company may pursue.

2022 Q3 Financial Highlights

- **R&D Expenses**: Research and development expenses were $25.0 million for the quarter ended September 30, 2022, compared to $17.9 million for the same period in 2021. For the nine months ended September 30, 2022, research and development expenses were $81.2 million compared to $60.0 million for the same period in 2021. Research and development expenses increased primarily due to the continued progress of the Company's GATHER2 trial, increased manufacturing activities for ACP, and increases in personnel costs, including share-based compensation associated with additional research and development staffing, offset by decreases in costs associated with the Company's gene therapy programs.
- **G&A Expenses**: General and administrative expenses were $17.5 million for the quarter ended September 30, 2022, compared to $6.6 million for the same period in 2021. For the nine months ended September 30, 2022, general and administrative expenses were $45.8 million compared to $21.7 million for the same period in 2021. General and administrative expenses increased primarily due to increases in personnel costs, including share-based compensation associated with staffing for commercial preparation.
- **Net Loss**: The Company reported a net loss for the quarter ended September 30, 2022, of $42.4 million, or ($0.35) per diluted share, compared to a net loss of $24.6 million, or $(0.23) per diluted share, for the same period in 2021. For the nine months ended September 30, 2022, the Company reported a net loss of $126.2 million or ($1.05) per diluted share, compared to a net loss of $81.5 million or ($0.84) for the same period in 2021.

Conference Call/Webcast 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 3, 2022, at 8:00 a.m. Eastern Time. To participate in this conference call, dial 1-888-317-6003 (USA) or 1-412-317-6061 (International), passcode 8170771. 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 1-877-344-7529 (USA Toll Free), passcode 6056402.

About Iveric Bio

Iveric Bio is a science-driven biopharmaceutical company focused on the discovery and development of novel treatments for retinal diseases with significant unmet medical needs. The Company is committed to having a positive impact on patients' lives by delivering high-quality, safe and effective treatments designed to address debilitating retinal diseases including earlier stages of age-related macular degeneration.

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 the robustness and clinical relevance of the clinical data from its GATHER1 and GATHER2 trials of ACP in GA, its development and regulatory strategy for ACP and its other product candidates, including its plans to submit an NDA to the U.S. Food and Drug Administration and an MAA to the European Medicines Agency for ACP and its plans for evaluating ACP in patients with intermediate AMD, 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 sustained release delivery technologies for ACP, its projected use of cash, cash equivalents, marketable securities and its committed loan facilities and the sufficiency of its cash resources, and statements regarding the Company's commercial plans and 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, expectations for regulatory matters, interpretation of clinical trial results by the scientific and medical community, the initiation, progress and success of research and development programs and clinical trials, reliance on clinical trial sites, contract development and manufacturing organizations and other third parties, developments from the Company's competitors, and the marketplace for the Company's products, need for and availability of 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 may 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,	
	2022	**2021**	**2022**	**2021**
Statements of Operations Data:				
Operating expenses:				
Research and development	$ 24,967	$ 17,935	$ 81,171	$ 59,972
General and administrative	17,545	6,648	45,764	21,688
Total operating expenses	42,512	24,583	126,935	81,660
Loss from operations	(42,512)	(24,583)	(126,935)	(81,660)
Interest income, net	200	42	815	184
Other expense, net	(39)	(10)	(30)	(13)
Loss before income tax benefit	(42,351)	(24,551)	(126,150)	(81,489)
Income tax benefit	-	-	-	-
Net loss	$ (42,351)	$ (24,551)	$ (126,150)	$ (81,489)
Net loss per common share:				
Basic and diluted	$ (0.35)	$ (0.23)	$ (1.05)	$ (0.84)
Weighted average common shares outstanding:				
Basic and diluted	120,277	105,217	119,578	97,370

	September 30, 2022	**December 31, 2021**
	(in thousands)	
Balance Sheets Data:		
Cash, cash equivalents and marketable securities	$ 320,535	$ 381,749
Total assets	$ 331,790	$ 389,358
Term loan, net	$ 47,649	$ -
Total liabilities	$ 72,264	$ 28,830
Additional paid-in capital	$ 1,065,545	$ 1,040,098
Accumulated deficit	$ (805,745)	$ (679,595)

Total stockholders' equity	$	259,526	$	360,528

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