



Iveric Bio and DelSiTech Enter Exclusive Agreement for Development of Sustained Release Zimura®

July 5, 2022

PARSIPPANY, N.J. & TURKU, Finland--(BUSINESS WIRE)--Jul. 5, 2022-- [IVERIC bio, Inc.](#) (Nasdaq: ISEE) and DelSiTech Ltd, announced today an exclusive global license agreement providing Iveric Bio with the right to develop and commercialize new formulations of Zimura® (avacincaptad pegol) using DelSiTech's silica-based sustained release technology. As part of Iveric Bio's lifecycle expansion plan for Zimura, the Company is committed to developing sustained release technologies for the treatment of age-related macular degeneration (AMD). These technologies potentially could address patients being treated for geographic atrophy (GA) and intermediate AMD.

"We are thrilled to collaborate with the DelSiTech team on investigating additional sustained release formulations for Zimura with their drug delivery expertise and advanced technology and look forward to evaluating a sustained release formulation in GA and potentially earlier stages of AMD," stated Pravin U. Dugel, MD, President of Iveric Bio. "Previously reported post-hoc analyses from GATHER1 suggest that Zimura may have the potential to impact AMD in early stages before atrophy occurs in patients. We believe Zimura, which is a chemically synthesized RNA aptamer, is amenable to injectable sustained release formulations."

"As a leading developer of long-acting controlled release formulations for small molecules and biological entities, we are excited about collaborating with Iveric Bio on bringing innovative solutions to patients living with AMD," stated Lasse Leino, PhD, Chief Executive Officer of DelSiTech. "We are inspired by the opportunity to leverage our drug delivery technology to potentially help AMD patients early and improve their treatment experience."

"This agreement underscores our commitment to invest in lifecycle initiatives for Zimura," said Glenn P. Sblendorio, Chief Executive Officer of Iveric Bio. "We are excited about the possibilities to expand Zimura into earlier stages of AMD and potentially allow for a next-generation treatment to help patients with GA."

"We are proud to bring our competencies into this promising alliance and contribute to Iveric Bio's mission to address unmet needs for patients," said Dr. Frederic Dargelas, Head of Business Development and Alliance Management for DelSiTech.

Under the terms of the license agreement, Iveric Bio will pay DelSiTech an upfront payment of €1,250,000, as well as development and commercial milestones and royalties on net sales of licensed products.

In addition to working with DelSiTech, Iveric Bio plans to explore the potential for Zimura in earlier stages of AMD by initiating a clinical trial studying the current formulation of Zimura in patients with intermediate AMD in the fourth quarter of 2022. The development strategy in this indication is subject to global regulatory feedback from the U.S. Food and Drug Administration (FDA) and other regulatory authorities, which Iveric Bio plans to obtain before initiating this trial.

About Zimura GATHER1 and GATHER2 Clinical Trials

Iveric Bio previously announced that GATHER1, the Company's first Phase 3 clinical trial for Zimura (avacincaptad pegol) for GA, met its pre-specified primary efficacy endpoint with statistical significance. The most frequently reported ocular adverse events in this trial were related to the injection procedure. The Company expects topline data for GATHER2, the Company's second Phase 3 clinical trial for Zimura for GA, to be available in the third quarter of 2022, approximately one year after the enrollment of the last patient in the trial plus the time needed for database lock and analysis. If 12-month results from GATHER2 are positive, the Company plans to submit applications with the FDA and the European Medicines Agency (EMA) for marketing approval of Zimura for GA. There are no FDA or EMA approved treatments available for patients with GA.

About Zimura

Zimura (avacincaptad pegol) is an investigational drug product and has not been approved for use anywhere globally. Zimura is designed to target and inhibit the cleavage of complement protein C5 and the formation of its downstream fragments, C5a and C5b. By inhibiting the formation of these fragments, Zimura is believed to decrease or slow the chronic inflammation and cell death associated with the retinal aging process by decreasing the formation of membrane attack complex (MAC) and inflammasome activity, thereby potentially avoiding or slowing the degeneration of retinal pigment epithelial cells. This potential mechanism is the rationale for Zimura as a potential therapy for GA and earlier stages of AMD.

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. For more information on the Company, please visit www.ivericbio.com.

About DelSiTech

DelSiTech Ltd., located in Turku, Finland, is the leading technology specialist in biodegradable silica-based controlled release of small molecule drugs, biologics, and viral vectors. It develops and commercializes its proprietary, drug delivery technology in collaboration with a number of pharma and biotech companies to turn their ideas into novel drug products. For more information, see www.delsitech.com.

Iveric Bio Forward-looking Statements

Any statements in this press release about Iveric Bio'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 its development and regulatory strategy for Zimura, including the timing of receipt of topline data from the GATHER2 clinical trial, its ability to use its completed GATHER1 trial as a Phase 3 trial for purposes of seeking regulatory approval, its plans to file for marketing approval for geographic atrophy (GA) if the results of GATHER2 are positive, its plans for initiating a clinical trial studying Zimura in patients with intermediate AMD, the potential utility of Zimura, the Company's hypotheses regarding the role of complement inhibition in potentially treating AMD, the clinical meaningfulness of clinical trial results and data, including from post-hoc analyses of the GATHER1 clinical trial, and its business development and lifecycle management strategies. 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 progress and success of research and development programs and clinical trials, developments from the scientific and medical community, expectations for regulatory matters, reliance on clinical trial sites, contract development and manufacturing organizations and other third parties, establishment of manufacturing capabilities, need for additional financing, 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.

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Investor Contact:

Kathy Galante
Senior Vice President, Investor Relations
kathy.galante@ivericbio.com

or

Media Contact:

Jeannie Neufeld
Senior Director, Public Relations & Communications
jeannie.neufeld@ivericbio.com

Source: IVERIC bio, Inc.