



Qlaris Bio Reports Phase 2 Clinical Trial Results Demonstrating Favorable Safety and Tolerability Profile and Positive Efficacy Signal for QLS-101

Findings from First-in-Human Study Support Continued Clinical Development of Investigational IOP-lowering Therapy; New Trials Planned as Complementary Glaucoma Treatment and in Rare Pediatric Indication

Wellesley, Mass., May 18, 2022 – [Qlaris Bio, Inc.](#) (the “Company” or “Qlaris”), a biotechnology company targeting high unmet needs in debilitating ophthalmic diseases, today announced results from QC-201, a first-in-human, Phase 2 clinical trial of QLS-101, the Company’s investigational therapy for lowering intraocular pressure (IOP) in the treatment of glaucoma. Study findings demonstrated a favorable safety and tolerability profile for QLS-101, including no evidence of hyperemia (eye redness), as well as a positive efficacy signal, in patients with primary open-angle glaucoma (POAG) or ocular hypertension.

These data support the ongoing clinical development of QLS-101 and Qlaris intends to initiate several new studies designed to further assess the potential role of the compound as a first-in-class glaucoma treatment. Additional clinical trials will seek to evaluate QLS-101 as a complementary therapy to available glaucoma treatments and procedures, such as prostaglandin analogs and minimally invasive glaucoma surgery (MIGS), and as a treatment for juvenile patients with Sturge-Weber syndrome (SWS)-related glaucoma.

QLS-101 is a novel adenosine triphosphate (ATP)-sensitive potassium (K_{ATP}) channel modulator administered as a topical eyedrop. Unlike currently available therapies for lowering IOP in glaucoma, QLS-101 targets distal outflow resistance and episcleral venous pressure (EVP), a key component of IOP. QLS-101 improves the outflow of aqueous humor by widening outflow channels and the episcleral vessels of the eye distal to the trabecular meshwork to lower IOP.

“These Phase 2 data are encouraging, particularly the absence of hyperemia, which is a common side effect with certain glaucoma treatments and one which can lead patients to discontinue therapy,” said Thurein Htoo, MS, MBA, chief executive officer and co-founder of Qlaris Bio. “With the well-tolerated safety profile and efficacy signal demonstrated in this study, we believe QLS-101 can serve as a compelling complement to existing drugs and drainage devices to help patients for whom EVP and distal outflow resistance may be pathologic or treatment-limiting.”

“As a clinician, I often see glaucoma patients whose vision loss continues to progress even when treated with current therapeutic options that target different components of IOP than



EVP,” said Barbara Wirostko, MD, FARVO, chief medical officer and co-founder of Qlaris Bio. “QLS-101 may provide a first-in-class mechanism of action to lower IOP by focusing on resistance distal to the trabecular meshwork of the eye that is not yet fully addressed by available therapies. We look forward to initiating additional studies pursuing these new solutions.”

POAG is the most common adult form of glaucoma and remains one of the leading causes of preventable blindness worldwide. Elevated IOP remains the only modifiable risk factor for progression of glaucoma. Despite available therapies and surgical interventions, patients with POAG may not achieve IOP-lowering goals as available options only target three components of IOP. This leaves the fourth component of IOP — EVP — insufficiently addressed.

“The results from the QC-201 trial are promising and certainly should prompt continued study of the potential impact of this promising investigational therapy,” said Sharon F. Freedman, MD, professor of ophthalmology and pediatrics at Duke University Medical Center, and a principal investigator in ongoing Qlaris trials. “An EVP-targeting therapy could also address a significant unmet need for patients living with certain types of glaucoma, such as Sturge-Weber syndrome. I look forward to continued collaboration with Qlaris on this important work.”

SWS is a pediatric rare disease signified by a facial port wine birthmark. Individuals living with SWS often suffer from severe, intractable glaucoma in the eye on the same side as their birthmark. In these individuals, increased IOP is driven by pathologically elevated EVP. By directly lowering EVP, QLS-101 may be uniquely well-suited to address SWS and improve therapeutic outcomes.

About QLS-101

QLS-101, Qlaris Bio’s lead product candidate, is a prodrug of levcromakalim, an adenosine triphosphate (ATP)-sensitive potassium (K_{ATP}) channel modulator. By lowering episcleral venous pressure (EVP) and increasing aqueous humor outflow through vessels distal to the trabecular meshwork, QLS-101 may be able to uniquely address diseases of pathologic EVP resulting in elevated intraocular pressure (IOP), such as Sturge-Weber syndrome-related glaucoma, and diseases where EVP limits maximal therapy, including primary open-angle glaucoma and normal-tension glaucoma. QLS-101 was invented at Mayo Clinic and the University of Minnesota and is being developed under an exclusive worldwide license.

About Qlaris Bio, Inc.

Qlaris Bio, Inc. was founded in August 2019 with a singular focus: to develop novel, innovative therapies with first-in-class mechanisms of action to address serious and debilitating



ophthalmic diseases. The company's lead platform is based on the use of adenosine triphosphate (ATP)-sensitive potassium (K_{ATP}) channel modulators to affect the tone of vascular and vascular-like tissues, initially focused on ophthalmic use. Qlaris Bio's investors include Canaan and New Leaf Venture Partners, both of which were co-lead investors in the company's \$25 million Series A round in August 2019. Other investors include Correlation Ventures and Mayo Clinic. For more information, please visit qlaris.bio.

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