Qlaris Bio Enrolls First Patient in Phase 1/2 Studies of QLS-101, an Investigational Therapy Designed to Lower Episcleral Venous Pressure (EVP) in Patients with Glaucoma

- Phase 1/2 Initiation Follows FDA Acceptance of Investigational New Drug (IND) Application -

Wellesley, Mass., April 15, 2021 -- Qlaris Bio, Inc., a biotechnology company targeting high unmet needs in debilitating ophthalmic diseases, today announced the enrollment of the first patient in the Phase 1/2 clinical program for QLS-101, an investigational therapy designed to lower intraocular pressure (IOP) by reducing episcleral venous pressure (EVP) in individuals with 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 specifically lowers EVP, a key determinant of IOP, or fluid pressure in the eye, which can be elevated in individuals with glaucoma. Beyond its potential utility as an effective monotherapy or additive therapy for the lowering of IOP in primary open angle glaucoma (POAG), QLS-101 may represent a new treatment paradigm in additional populations where current IOP-lowering therapies are inadequate, including normal-tension glaucoma (NTG) and patients with Sturge-Weber syndrome (SWS, a rare pediatric disease).

“This milestone marks the arrival of Qlaris Bio as a clinical-stage company. Our team has advanced QLS-101 to an IND filing in just 18 months following the founding of our company with a $25 million Series A financing co-led by Canaan and New Leaf Venture Partners. The unique profile of QLS-101 has generated strong interest in an EVP-lowering therapy among leading ophthalmologists, researchers, patients, and investors,” said Thurein Htoo, MS, MBA, chief executive officer and co-founder of Qlaris Bio. “Our rapid advance into the clinic was built on the innovative research of Professor Michael Fautsch, PhD, at Mayo Clinic and the Qlaris team’s ophthalmic drug development expertise.”

QLS-101 improves the outflow of aqueous humor, the fluid that maintains pressure in the eye. It does so by widening outflow channels and episcleral vessels distal to, or away from, the trabecular meshwork, a mesh-like structure that serves as the eye’s drainage system, to lower IOP.

“By reducing EVP, QLS-101 represents a unique approach to enable the achievement of even lower IOP targets than available therapies currently allow,” commented Barbara Wirostko, MD,

chief medical officer and co-founder of Qlaris Bio. “The availability of a once-daily topical eyedrop formulation that targets EVP would help address a key component of the IOP puzzle that current medical management may not adequately address, particularly in underserved patient populations.”

QLS-101 Phase 1/2 Clinical Program

Qlaris Bio enrolled the first patient in Study QC-201, a multi-center, randomized, double-masked, active-controlled study comparing three concentrations of once-daily topical QLS-101 to timolol maleate preservative-free (PF) ophthalmic solution, a conventional glaucoma therapeutic. For more information, visit clinicaltrials.gov and use the identifier NCT04830397 for Study QC-201. The QLS-101 clinical program also includes two additional Phase 1/2 studies scheduled to start later this year in patients with normal tension glaucoma and in adult subjects with Sturge Weber syndrome-related glaucoma.

About QLS-101

QLS-101, Qlaris Bio’s lead product candidate, is a novel prodrug of levcromakalim, an ATP-sensitive potassium (KATP) 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 novel 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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