

QLS-111 SAFELY AND EFFECTIVELY LOWERED INTRAOCULAR PRESSURE IN TWO PHASE 2 CLINICAL TRIALS, OSPREY AND APTERYX

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Lowering episcleral venous pressure (EVP) offers an innovative approach for reducing intraocular pressure (IOP) in patients with glaucoma and ocular hypertension (OHT). QLS-111, a novel ATP-sensitive potassium channel opener formulation, lowers IOP by enhancing distal outflow through vasorelaxation and directly reducing EVP. Two randomized, controlled, double-masked Phase 2 studies evaluated the safety, tolerability, and efficacy of QLS-111 at three concentrations with two dosing regimens in patients with primary open-angle glaucoma (POAG) or OHT.

In Osprey (NCT06016972), 62 patients were washed out of IOP-lowering therapies and randomized to QLS-111 (0.015%, 0.030%, or 0.075%) or vehicle for 21 days. Dosing progressed from once-daily morning (QAMx7days) to evening (QPMx7days) and then twice daily (BIDx7days). In Apteryx (NCT06249152), 32 patients controlled on latanoprost with IOP \geq 19 mmHg received QLS-111 or vehicle QPM for 14 days, then BID for 14 days. IOP was measured at 3 time points and safety was assessed via adverse events (AEs), vital signs, and ophthalmic exams.

Participants (52% male) averaged 67.3 years of age. In Osprey, QLS-111 at 0.015% and 0.030% produced significant mean diurnal IOP reductions. Baseline IOPs were 23.0 mmHg (0.015%), 23.7 mmHg (0.030%), 24.1 mmHg (0.075%), and 24.2 mmHg (vehicle). QLS-111 (0.015%) lowered IOP by 2.8 mmHg (QAM, $p=0.0018$), 3.7 mmHg (QPM, $p=0.0001$), and 2.8 mmHg (BID, $p=0.0018$). In Apteryx, 0.015% QLS-111 concomitant with latanoprost reduced IOP by 3.2 mmHg (QPM, $p=0.0005$) and 3.6 mmHg (BID, $p=0.0002$) from a baseline of 19.8 mmHg. No serious AEs were reported in either study. Mild hyperemia and irritation occurred only in higher-dose (0.075%) and vehicle groups. No treatment-related AEs were seen with 0.015%.

QLS-111 was well tolerated and effectively reduced IOP in POAG and OHT, showing significant additive effects with concomitant latanoprost. Further development of QLS-111 as monotherapy or fixed dose combination, including for normal tension glaucoma is currently underway.