SHATTER EXPECTATIONS

iDose[®] TR[®] (travoprost intracameral implant) 75 mcg

iDose TR is an intracameral procedural pharmaceutical therapy that delivers prostaglandin analog therapy for the reduction of intraocular pressure (IOP) in patients with open-angle glaucoma (OAG) or ocular hypertension (OHT).¹

Phase 3 Trial Design

To evaluate iDose TR efficacy and safety in patients with OHT and OAG. Two identically-designed Phase 3, parallel-group, double-masked, randomized, prospective, sham-controlled trials compared iDose TR to topical timolol (0.5%) BID. N=1150; 89 trial sites^{2*}

Proven Performance in Clinical Trials

In two pivotal trials, iDose TR achieved the pre-specified primary efficacy endpoint (non-inferiority to topical timolol through 3 months).²

Primary Endpoint: Change from baseline in diurnal IOP (vs timolol) through 3 months postoperative.^{2**}



Change from time-matched baseline in IOP at 8AM and 10AM at Day 10, Week 6 and Month 3. Baseline was 24.6 mmHg.

81%

of iDose TR patients were completely free of IOP-lowering topical medications at 12 months.²

Superior IOP Reduction vs Pre-Trial PGA



iDose TR demonstrated 1.3 mmHg statistically superior IOP-lowering vs pre-trial PGAs (p=0.0003).²

Pharmacokinetic Clinical Trial Demonstrated Durability⁺



- Mean TFA levels were above topical medication C_{max} concentration (1.78 ng/mL) and implant efficacy TFA level (0.095 ng/mL) at all time points.³
- The 16% of remaining travoprost in iDose TR implants explanted at 24 months indicates the potential for drug delivery beyond 2 years.³

Phase 2b Trial: Outcomes Demonstrated Through 36 Months[‡]

69%

of iDose TR patients were well controlled[‡] on same or fewer prescription eye drops in the Phase 2b trial at 36 months.⁴

Safety Data

The most commonly reported ocular adverse reactions (2% to 6%) were increases in intraocular pressure, iritis, dry eye, visual field defects, eye pain, ocular hyperemia, and reduced visual acuity.¹ For additional safety information refer to IMPORTANT SAFETY INFORMATION below.



No clinically significant endothelial cell loss No periorbital fat atrophy No serious corneal AEs **No DSAEK**

No DMEK

1. iDose TR (travoprost intracameral implant) 75 mcg Prescribing Information. Glaukos Corporation. 2023. 2. iDose TR Phase 3 Clinical Trials, data on file, Glaukos Corporation. 3. iDose TR Pharmacokinetic Clinical Study, data on file, Glaukos Corporation. 4. Berdahl JP, et al. Efficacy and Safety of the Travoprost Intraocular Implant in Reducing Topical IOP-Lowering Medication Burden in Patients with Open-Angle Glaucoma or Ocular Hypertension. Drugs. 2023 Dec 7. doi: 10.1007/s40265-023-01973-7. PMID: 38060092.

- Inclusion Criteria: Patients 18 years or older; diagnosed with open-angle glaucoma (POAG, PXG or PG) or ocular hypertension; C/D ratio < 0.8; zero to three preoperative ocular hypotensive medications; BSCVA of 20/80 or better
- ** Change from time-matched baseline in IOP at 8AM and 10AM at Day 10, Week 6 and Month 3.
- Diose TR clinical results shown represent the approved and commercially marketed version; identified as the "slow-eluting implant arm" in the pivotal trials. Pharmacokinetic Trial Design: Open label, single-center trial, separate from the pivotal trials, to determine in-patient drug elution rate and aqueous humor (AH) exposure to travoprost free acid (TFA).
- Pharmacokinetic Irial Design: Open label, single-center trial, separate from the pivotal trials, to determine in-patient drug elution rate and aqueous numor (AH) exposure to travoprost tree acid (TA). 210 iDose TR (travoprost intracameral implant) 75 mcg patients; 14 cohorts followed for 3-24 months. At pre-determined timepoints, AH was collected to analyze TFA concentrations and iDose TR was removed to determine remaining level of travoprost in the explants. Patients were on topical PGA monotherapy (bimatoprost, latanoprost, latanoprostene bunod, tafluprost, or travoprost) at screening. Intent to Treat: 133 patients, I25 iDose TR patients analyzed at 3 months. **Phase 2b Trial Design:** To assess iDose TR for safety and efficacy for reduction of elevated IOP, 154 patients with OAG or OHT were studied in a prospective, randomized, double-masked, multi-center trial. A single administration of 10 Dose TR compared to topical timolol ophthalmic solution, 0.5% twice per day. **Well controlled:** Pressure of 18 mmHg and below

*** Inclusive of Phase 3 and Phase 2b trials

INDICATIONS AND USAGE

iDose TR (travoprost intracameral implant) is indicated for the reduction of intraocular pressure (IOP) in patients with open angle glaucoma (OAG) or ocular hypertension (OHT).

IMPORTANT SAFETY INFORMATION

DOSAGE AND ADMINISTRATION

For ophthalmic intracameral administration. The intracameral administration should be carried out under standard aseptic conditions.

CONTRAINDICATIONS

iDose TR is contraindicated in patients with active or suspected ocular or periocular infections, patients with corneal endothelial cell dystrophy (e.g., Fuch's Dystrophy, corneal guttatae), patients with prior corneal transplantation, or endothelial cell transplants (e.g., Descemet's Stripping Automated Endothelial Keratoplasty [DSAEK]), patients with hypersensitivity to travoprost or to any other components of the product.

WARNINGS AND PRECAUTIONS

iDose TR should be used with caution in patients with narrow angles or other angle abnormalities. Monitor patients routinely to confirm the location of the iDose TR at the site of administration. Increased pigmentation of the iris can occur. Iris pigmentation is likely to be permanent.

ADVERSE REACTIONS

In controlled studies, the most common ocular adverse reactions reported in 2% to 6% of patients were increases in intraocular pressure, iritis, dry eye, visual field defects, eye pain, ocular hyperaemia, and reduced visual acuity.

Please see full <u>Prescribing Information</u>. You are encouraged to report all side effects to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088. You may also call Glaukos at 1-888-404-1644.



View full prescribing information at iDoseTRhcp.com





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