

## iDose® TR (travoprost intracameral implant) – New drug approval

- On December 14, 2023, <u>Glaukos announced</u> the FDA approval of <u>iDose TR (travoprost intracameral implant)</u>, for the reduction of intraocular pressure (IOP) in patients with open-angle glaucoma (OAG) or ocular hypertension (OHT).
- iDose TR is designed to continuously deliver therapeutic levels of a proprietary formulation of travoprost inside the eye for extended periods of time.
- The efficacy of iDose TR was established in two randomized, double-masked, controlled clinical trials in patients with OAG or OHT. In both trials, iDose TR was compared to twice-daily topical administration of timolol maleate ophthalmic solution, 0.5%.
  - In the first 3 months following administration, iDose TR demonstrated an IOP change from baseline of -6.6 to -8.4 mmHg in the study eye of patients with a mean baseline IOP of 24 mmHg.
  - iDose TR demonstrated non-inferiority to timolol ophthalmic solution in IOP reduction during the first 3 months. Subsequently, iDose TR did not demonstrate non-inferiority over the next 9 months.
- iDose TR is contraindicated in patients with:
  - Active or suspected ocular or periocular infections
  - Corneal endothelial cell dystrophy (eg, Fuch's Dystrophy, corneal guttatae)
  - Prior corneal transplantation, or endothelial cell transplants (eg, Descemet's Stripping Automated Endothelial Keratoplasty)
  - Hypersensitivity to travoprost or to any other components of the product.
- Warnings and precautions for iDose TR include iridocorneal angles; device dislocation; macular edema; intraocular inflammation; pigmentation; endophthalmitis; and magnetic resonance imaging (MRI) conditional.
- The most common adverse reactions with iDose TR use were increased intraocular pressure, iritis, dry eye, and visual field defects.
- iDose TR is a travoprost delivery system consisting of a travoprost releasing implant pre-loaded in a sterile, single-dose inserter. iDose TR is administered intracamerally through a small, clear corneal incision and is anchored into the sclera at the iridocorneal angle.
  - iDose TR should not be readministered to an eye that received a prior iDose TR
- Glaukos plans to launch iDose TR in the latter part of the first quarter of 2024. iDose TR will be available as an intracameral implant containing 75 mcg travoprost.

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