Durysta™ (bimatoprost implant) – New drug approval

- On March 5, 2020, Allergan announced the FDA approval of Durysta (bimatoprost implant), for the reduction of intraocular pressure (IOP) in patients with open angle glaucoma (OAG) or ocular hypertension (OHT).

- Durysta, a prostaglandin analog, is the first intracameral, biodegradable sustained-release implant for patients with OAG or OHT.

- Bimatoprost is also available generically as an ophthalmic solution for the same indication as Durysta.

- The efficacy of Durysta was established in two randomized, controlled 20-month studies of Durysta compared to twice daily topical timolol 0.5% drops, in patients with OAG or OHT.

    — Durysta demonstrated an IOP reduction of approximately 5 to 8 mmHg in patients with a mean baseline IOP of 24.5 mmHg.

- Durysta is contraindicated in patients with:

    — Active or suspected ocular or periocular infections
    — Corneal endothelial cell dystrophy (eg, Fuchs' Dystrophy)
    — Prior corneal transplantation, or endothelial cell transplants (eg, Descemet's Stripping Automated Endothelial Keratoplasty)
    — Posterior lens capsule that is absent or ruptured, due to the risk of implant migration into the posterior segment
    — Hypersensitivity to bimatoprost or to any other components of the product.

- Warnings and precautions for Durysta include corneal adverse reactions, iridocorneal angle, macular edema, intraocular inflammation, pigmentation, and endophthalmitis.

- The most common ocular adverse reaction (in 27%) with Durysta use was conjunctival hyperemia. Other common adverse reactions (5% to 10%) with Durysta use were foreign body sensation, eye pain, photophobia, conjunctival hemorrhage, dry eye, eye irritation, increased IOP, corneal endothelial cell loss, blurred vision, iritis, and headache.

- Durysta is an ophthalmic drug delivery system for a single intracameral administration of a biodegradable implant. Durysta should not be readministered to an eye that received a prior Durysta.

    — The intracameral administration should be carried out under standard aseptic conditions.
    — Refer to the Durysta drug label for additional administration recommendations.

- Allergan's launch plans for Durysta are pending. Durysta will be available as an intracameral implant containing 10 mcg of bimatoprost in a drug delivery system.