Dextenza® (dexamethasone ophthalmic insert) – New drug approval

- On December 3, 2018, Ocular Therapeutix announced the FDA approval of Dextenza (dexamethasone ophthalmic insert), for the treatment of ocular pain following ophthalmic surgery.

- Dextenza is the first preservative-free corticosteroid intracanalicular insert. Dextenza is placed in the punctum, a natural opening in the inner portion of the lower eyelid, and into the canaliculus.

- The efficacy of Dextenza was based on two vehicle-controlled studies enrolling 488 patients. Dextenza or its vehicle was placed immediately after cataract surgery.

    — In both studies, Dextenza had a higher incidence of patients who were pain free at post-operative days 2, 4 and 8.

- Dextenza is contraindicated in patients with active corneal, conjunctival or canalicular infections, including epithelial herpes simplex keratitis (dendritic keratitis), vaccinia, varicella; mycobacterial infections; fungal diseases of the eye, and dacryocystitis.

- Other warnings and precautions of Dextenza include intraocular pressure increase, bacterial infection, viral infections, fungal infections, and delayed healing.

- The most common adverse reactions (5 – 9%) with Dextenza use were anterior chamber inflammation and elevations in intraocular pressure.

- The recommended dose of Dextenza is one ophthalmic insert that is inserted in the lower lacrimal punctum into the canaliculus by a physician. A single Dextenza releases a 0.4 mg dose of dexamethasone for up to 30 days following insertion.

    — Dextenza is resorbable and does not require removal.
    — Saline irrigation or manual expression can be performed to remove the insert if necessary.

- Ocular Therapeutix's launch plans for Dextenza are pending. Dextenza will be available as an ophthalmic intracanalicular insert containing a 0.4 mg dose of dexamethasone.