Dextenza® (dexamethasone ophthalmic insert) – New indication

- On October 11, 2021, Ocular Therapeutix announced the FDA approval of Dextenza (dexamethasone ophthalmic insert), for the treatment of ocular itching associated with allergic conjunctivitis.

- Dextenza is also approved for the treatment of ocular inflammation and pain following ophthalmic surgery.

- The approval of Dextenza for the new indication was based on three randomized, double-masked, vehicle-controlled efficacy studies in 255 patients with itching associated with allergic conjunctivitis. Patients received Dextenza or its vehicle utilizing a repeat conjunctival allergen challenge mode.

    — In all three trials, Dextenza resulted in lower mean ocular itching scores compared with the vehicle group at all time points throughout the one-month duration of the study. In two of the three studies, a higher proportion of patients had statistically significant reductions in ocular itching on day 8, at 3 minutes, 5 minutes, and 7 minutes post-challenge in the Dextenza group than in the vehicle group.
    — Refer to the Dextenza drug label for complete study results.

- Dextenza is an ophthalmic insert that is inserted in the lower lacrimal punctum into the canaliculus. A single Dextenza insert 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. Dextenza is intended for single-use only.