Eysuvis™ (loteprednol etabonate) – New drug approval

- On October 27, 2020, Kala Pharmaceuticals announced the FDA approval of Eysuvis (loteprednol etabonate) 0.25% ophthalmic suspension, for the short-term (up to two weeks) treatment of the signs and symptoms of dry eye disease.

- Eysuvis is the first ocular corticosteroid approved for dry eye disease.

- Loteprednol etabonate is also available as a single-ingredient product in several other ophthalmic formulations, including: a generic 0.5% ophthalmic suspension, Alrex® 0.2% ophthalmic suspension, Inveltys® 1% ophthalmic suspension, Lotemax® 0.5% ophthalmic gel, Lotemax SM 0.38% ophthalmic gel, and Lotemax 0.5% ophthalmic ointment.

    - The generic 0.5% ophthalmic suspension is approved for steroid-responsive inflammatory conditions and for the treatment of post-operative inflammation following ocular surgery.
    - Alrex is approved for temporary relief of the signs and symptoms of seasonal allergic conjunctivitis.
    - Inveltys, Lotemax gel, Lotemax SM gel, and Lotemax ointment are approved for the treatment of post-operative inflammation and pain following ocular surgery.

- The efficacy of Eysuvis was established in four randomized, double-masked, placebo-controlled studies in 2,900 patients with dry eye disease. Patients received Eysuvis or vehicle four times a day for 2 weeks. Ocular discomfort severity (ODS) was rated by patients daily over the course of the trial using a visual analog scale (0 = very mild, 100 = very severe). Conjunctival hyperemia was graded using the Cornea and Contact Lens Research Unit (CCLRU) grading scale (0 = none; 1 = very slight; 2 = slight; 3 = moderate; 4 = severe).

    - A larger reduction in ODS favoring Eysuvis was observed at day 15 in the patient population.
    - A larger reduction in hyperemia favoring Eysuvis was observed at day 15 in all four trials.

- Eysuvis is contraindicated in most viral diseases of the cornea and conjunctiva including epithelial herpes simplex keratitis (dendritic keratitis), vaccinia, and varicella, and also in mycobacterial infection of the eye and fungal diseases of ocular structures.

- Warnings and precautions for Eysuvis include delayed healing and corneal perforation; increased intraocular pressure (IOP); cataracts; bacterial infections; viral infections; fungal infections; risk of contamination; and contact lens wear.

- The most common adverse reaction with Eysuvis use was instillation site pain, which was reported in 5% of patients.

- The recommended dose of Eysuvis is one to two drops instilled into each eye four times daily for up to two weeks. This product should only be renewed after examination under magnification such as a slit lamp and evaluation of the IOP.

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- Kala Pharmaceuticals plans to launch Eysuvis by year-end. Eysuvis will be available as a 2.5 mg/mL ophthalmic suspension.

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