Inveltys™ (loteprednol etabonate) – New drug approval

- On August 23, 2018, Kala Pharmaceuticals announced the FDA approval of Inveltys (loteprednol etabonate) 1% ophthalmic suspension, for the treatment of post-operative inflammation and pain following ocular surgery.
    - Inveltys is the first twice-daily ocular corticosteroid approved for this indication; all other ocular steroids are only approved for four-times-a-day dosing.
    - Inveltys utilizes Kala's proprietary Mucus-Penetrating Particle (MPP) technology to enhance penetration into target tissues of the eyes.
- Loteprednol etabonate is also available for ophthalmic use as the branded products Alrex® 0.2% suspension, Lotemax® 0.5% suspension, Lotemax 0.5% gel, Lotemax 0.5% ointment, and as a combination suspension Zylet® (loteprednol 0.5%/tobramycin 0.3%).
    - Alrex is indicated for the temporary relief of the signs and symptoms of seasonal allergic conjunctivitis.
    - Lotemax suspension is indicated for certain steroid-responsive inflammatory conditions when the inherent hazard of steroid use is accepted to obtain an advisable diminution in edema and inflammation, including the treatment of post-operative inflammation following ocular surgery.
    - Lotemax gel and ointment are indicated only for post-operative inflammation and pain following ocular surgery.
    - Zylet is indicated for steroid-responsive inflammatory ocular conditions for which a corticosteroid is indicated and where superficial bacterial ocular infection or a risk of bacterial ocular infection exists.
- The efficacy of Inveltys was evaluated in two clinical studies in which patients were assigned to Inveltys or placebo following ocular surgery. Complete resolution of inflammation and complete resolution of pain was assessed at 4, 8, and 15 days post-surgery.
    - A significant benefit was seen in the Inveltys-treated group for complete resolution of ocular inflammation at days 8 and 15, and complete resolution of pain at days 4, 8, and 15, when compared with placebo ($p < 0.01$ for all treatment comparisons).
- Inveltys 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.
- Other warnings and precautions of Inveltys include increased intraocular pressure, cataract formation, delayed healing, bacterial infections, viral infections, fungal infections, and contact lens wear.
- The most common adverse reactions with Inveltys use were eye pain (1%) and posterior capsular opacification (1%). These reactions may have been the consequence of the surgical procedure.
- The recommended dosage of Inveltys is one to two drops instilled into the affected eye twice daily beginning the day after surgery and continuing throughout the first 2 weeks of the post-operative periods. Shake for one to two seconds before using.

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- Kala plans to launch Inveltys in the beginning of 2019. Inveltys will be available as a sterile preserved ophthalmic suspension containing 10 mg/mL of loteprednol etabonate.