Clobetasol propionate ophthalmic suspension – New drug approval

- On March 4, 2024, Formosa Pharmaceuticals and AimMax Therapeutics announced the FDA approval of clobetasol propionate ophthalmic suspension, for the treatment of post-operative inflammation and pain following ocular surgery.

- This is the first FDA-approved ophthalmic clobetasol propionate product. Clobetasol propionate is a corticosteroid.

- The efficacy of clobetasol propionate was established in two randomized, double-masked, vehicle-controlled studies in 748 patients after cataract surgery. Clobetasol propionate or vehicle was self-administered twice a day for 14 days, beginning on the day after surgery. The co-primary endpoints were the proportion of patients with complete resolution of inflammation and complete resolution of pain.

    — In the intent-to-treat analysis, both coprimary efficacy endpoints were statistically significantly better in clobetasol propionate-treated patients compared to vehicle-treated patients ($p < 0.01$).

- Clobetasol propionate is contraindicated in most active 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 clobetasol propionate include increased intraocular pressure (IOP), cataracts; delayed healing; corneal and scleral melting; bacterial infections; viral infections; fungal infections; risk of contamination; and contact lens wear.

- The most common ocular adverse reactions (≥ 1%) with clobetasol propionate use were eye inflammation, corneal edema, anterior chamber inflammation, cystoid macular edema, IOP elevation, photophobia, and vitreous detachment. Many of these reactions may have been the consequence of the surgical procedure.

- The recommended dose of clobetasol propionate is one drop instilled into the affected eye twice daily beginning the day after surgery and continuing throughout the first 2 weeks of the post-operative period.

- Formosa Pharmaceuticals plans to launch clobetasol propionate by middle of 2024. Clobetasol propionate will be available as a 0.05% ophthalmic suspension.