Upneeq™ (oxymetazoline) – New drug approval

- On July 9, 2020, Osmotica Pharmaceuticals announced the FDA approval of Upneeq (oxymetazoline), for the treatment of acquired blepharoptosis in adults.

- Acquired blepharoptosis, also known as ptosis or droopy eyelid, is a unilateral or bilateral drooping of the upper eyelid that usually occurs from a partial or complete dysfunction of the muscles that elevate the upper eyelid. It can generally be classified as congenital or acquired, with the most common type being age-related aponeurotic ptosis.

- Upneeq is a direct-acting alpha adrenergic receptor agonist which is believed to selectively target Müller's muscle and elevate the upper eyelid. Upneeq is the first FDA-approved pharmacologic treatment indicated for the treatment of acquired blepharoptosis.

- The efficacy of Upneeq was established in two randomized, double-masked, vehicle-controlled studies in 304 patients with acquired blepharoptosis. Efficacy was assessed with the Leicester Peripheral Field Test (LPFT) (primary) and photographic measurement of Marginal reflex distance 1 (MRD1). The primary efficacy endpoints were ordered in a hierarchy to compare Upneeq to vehicle on the mean increase from baseline (day 1 hour 0) in number of points seen on the top 4 rows of the LPFT in the study eye at hour 6 on day 1 and hour 2 on day 14.

    — In study 1 at day 1 hour 6, the mean change from baseline LPFT in the Upneeq arm was 5.2 vs. 1.5 with vehicle (mean difference 3.7; 95% CI: 1.8, 5.6; $p < 0.01$). In study 2 at day 1 hour 6, the mean change from baseline in the Upneeq arm was 6.3 vs. 2.1 with vehicle (mean difference 4.2; 95% CI: 2.4, 6.1; $p < 0.01$).
    — In study 1 at day 2 hour 14, the mean change from baseline LPFT in the Upneeq arm was 6.4 vs. 2.2 with vehicle (mean difference 4.2; 95% CI: 2.0, 6.0; $p < 0.01$). In study 2 at day 2 hour 14, the mean change from baseline in the Upneeq arm was 7.7 vs. 2.4 with vehicle (mean difference 5.3; 95% CI: 3.7, 7.1; $p < 0.01$).
    — MRD1 showed a positive effect with Upneeq treatment. Greater MRD1 increases were observed for the Upneeq group than the vehicle group on day 1 at 6 hours post dose and on day 14 at 2 hours post dose.

- Warnings and precautions for Upneeq include potential impacts on cardiovascular disease, potentiation of vascular insufficiency, risk of angle closure glaucoma, and risk of contamination.

- The most common adverse reactions (1% to 5%) with Upneeq use were punctate keratitis, conjunctival hyperemia, dry eye, vision blurred, instillation site pain, eye irritation and headache.

- The recommended dose of Upneeq is one drop instillation into one or both ptotic eye(s) once daily.

    — The single patient-use container should be discarded immediately after dosing.
    — Contact lenses should be removed prior to instillation of Upneeq and may be reinserted 15 minutes following its administration.
    — If more than one topical ophthalmic drug is being used, the drugs should be administered at least 15 minutes between applications.

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- Osmotica plans to make Upneeq available next month to a selected group of ophthalmologists and optometrists through an early experience program plans. Upneeq will be available as a 0.1% oxymetazoline as salt ophthalmic solution.