Miebo™ (perfluorohexyloctane) – New drug approval

- On May 18, 2023, Bausch & Lomb announced the FDA approval of Miebo (perfluorohexyloctane), for the treatment of the signs and symptoms of dry eye disease (DED).

- DED affects millions of people in the U.S. A leading cause of DED is excessive tear evaporation, which due to an altered tear lipid layer, is often associated with the clinical signs of Meibomian gland dysfunction (MGD). An unstable tear film triggers increased ocular surface desiccation, inflammation, and damage to the ocular surface.

- Miebo is a novel eye drop that forms a monolayer at the air-liquid interface of the tear film which can be expected to reduce evaporation. The exact mechanism of action for Miebo in DED is not known.

- The efficacy of Miebo was established in two randomized, double-masked, saline-controlled studies (GOBI and MOJAVE) in 1,217 patients with a history of DED and clinical signs of MGD. Patients were randomized to Miebo or saline 0.6% for 57 days. The two primary endpoints were change from baseline at week eight (day 57 ± 2) in total corneal fluorescein staining (tCFS) and eye dryness score. tCFS was recorded at each study visit using a standardized grading system of 0 to 3 for each of the five areas on the cornea, totaling a maximum tCFS score for each eye of 15. Eye dryness score was rated by patients using a visual analogue scale (VAS) (0 = no discomfort, 100 = maximal discomfort).

    - In GOBI, the mean change from baseline in tCFS was -2.0 and -1.0 with Miebo and placebo, respectively (treatment difference -0.97, 95% CI: -1.40, -0.55). In MOJAVE, the mean change from baseline in tCFS was -2.3 and -1.1, respectively (treatment difference -1.21, 95% CI: -1.66, -0.76).
    - In GOBI, the mean change from baseline in eye dryness VAS was -27.4 and -19.7 with Miebo and placebo, respectively (treatment difference -7.61, 95% CI: -11.82, -3.40). In MOJAVE, the mean change from baseline in eye dryness VAS was -29.5 and -19.0, respectively (treatment difference -10.24, 95% CI: -14.35, -6.08).

- A warning and precaution for Miebo is use with contact lenses.

- The most common adverse reaction with Miebo use was blurred vision (reported in < 4% of individuals).

- The recommended dose of Miebo is one drop instilled four times daily into affected eye(s).

- Bausch & Lomb plans to launch Miebo in the second half of 2023. Miebo will be available as a 100% perfluorohexyloctane ophthalmic solution.