Tryptyr® (acoltremon) – New drug approval

- On May 28, 2025, Alcon announced the FDA approval of Tryptyr (acoltremon), for the **treatment of the signs and symptoms of dry eye disease (DED)**.

- Tryptyr is a **first-in-class TRPM8 receptor agonist** (neuromodulator) that stimulates corneal sensory nerves to rapidly increase natural tear production.

- The efficacy of Tryptyr was established in two randomized, double-masked, vehicle-controlled studies (COMET-2 and COMET-3) in a total of 931 patients with DED. Patients were randomized to Tryptyr or vehicle (placebo) for 90 days. Use of artificial tears was not allowed during the studies. The primary endpoint was the percentage of patients achieving ≥ 10 mm improvement from baseline in Schirmer score at day 14.

    - In COMET-2, the percentage of patients meeting the primary endpoint was 42.6% and 8.2% with Tryptyr and vehicle, respectively (difference 34.4, 95% CI: 26.9, 42.0; $p < 0.01$).
    - In COMET-3, the percentage of patients meeting the primary endpoint was 53.2% and 14.4% with Tryptyr and vehicle, respectively (difference 38.8, 95% CI: 30.8, 46.8; $p < 0.01$).

- Warnings and precautions for Tryptyr include potential for eye injury and contamination and use with contact lenses.

- The most common adverse reaction with Tryptyr use was instillation site pain.

- The recommended dose of Tryptyr is **one drop instilled in each eye twice daily** (approximately 12 hours apart).

- Alcon plans to launch Tryptyr in the third quarter of 2025. Tryptyr will be available as a 0.003% ophthalmic solution in single-dose vials.