Rhopressa® (netarsudil) – New drug approval

- On December 18, 2017, Aerie Pharmaceuticals announced the FDA approval of Rhopressa (netarsudil) 0.02% ophthalmic solution for the reduction of elevated intraocular pressure (IOP) in patients with open-angle glaucoma or ocular hypertension.

- Netarsudil is a rho kinase inhibitor, which is believed to reduce IOP by increasing the outflow of aqueous humor through the trabecular meshwork route.

- The efficacy and safety of Rhopressa were evaluated in three randomized, active-controlled studies of 1,416 patients with open-angle glaucoma or ocular hypertension.

    - The three studies demonstrated up to 5 mmHg reductions in IOP for patients treated with Rhopressa.
    - For patients with baseline IOP < 25 mmHg, the IOP reductions with Rhopressa dosed once daily were similar to those with timolol 0.5% dosed twice daily.
    - For patients with baseline IOP ≥ 25 mmHg, Rhopressa resulted in smaller mean IOP reductions at the morning time points than timolol 0.5% for study visits on days 43 and 90; the difference in mean IOP reduction between the two treatment groups was as high as 3 mmHg, favoring timolol.

- Warnings and precautions of Rhopressa include bacterial keratitis and use with contact lenses.
- The most common adverse reaction with Rhopressa use (53%) is conjunctival hyperemia. Other common adverse reactions (approximately 20%) include corneal verticillata, instillation site pain, and conjunctival hemorrhage.

- The recommended dose of Rhopressa is one drop in the affected eye(s) once daily in the evening.

- Aerie Pharmaceuticals plans to launch Rhopressa by mid-second quarter of 2018. Rhopressa will be available as a 0.02% (0.2mg/mL) ophthalmic solution.