## Rhofade™ (oxymetazoline) – New Drug Approval

- On January 19, 2017, Allergan announced the FDA approval of Rhofade (oxymetazoline) 1% cream, for the topical treatment of persistent facial erythema associated with rosacea in adults.

- Rosacea affects an estimated 16 million Americans. Persistent facial redness is cited as the most common sign of rosacea, and may resemble a flushing or sunburn that does not go away.

- The approval of Rhofade was based on two vehicle-controlled trials in 885 adult patients with moderate or severe rosacea.The primary efficacy endpoint was the proportion of patients with at least a 2-grade reduction in erythema from baseline on day 29 at hours 3, 6, 9, and 12.

    — In both clinical trials, more patients in the Rhofade arm achieved the primary endpoint compared to the vehicle arm.

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

- The most common adverse events (≥ 1%) with Rhofade use were application site dermatitis, worsening inflammatory lesions of rosacea, application site pruritus, application site erythema, and application site pain.

- The recommended topical dose of Rhofade is a pea-sized amount applied once daily, in a thin layer to cover the entire face (forehead, nose, each cheek and chin), avoiding the eyes and lips.

    — Rhofade is not for oral, ophthalmic, or intravaginal use.

- Allergan plans to launch Rhofade in May 2017. Rhofade will be available as a 1% topical cream.