Zerviate™ (cetirizine) – New drug approval

- On May 31, 2017, Nicox announced the FDA approval of Zerviate (cetirizine) ophthalmic solution for the treatment of ocular itching associated with allergic conjunctivitis.

- Allergic conjunctivitis causes eye redness, excessive watering, itchy burning eyes, discharge, blurred vision and increased sensitivity to light. Approximately 75 million people in the U.S. suffer from allergic conjunctivitis.

- Cetirizine is a second generation antihistamine (H1 receptor antagonist) that binds competitively to histamine receptor sites to reduce swelling, itching and vasodilation.

- Cetirizine is also available generically over the counter as an oral solution, oral tablets, oral chewable tablets, oral capsules, and in combination with pseudoephedrine.

- The efficacy of Zerviate was demonstrated in 3 placebo-controlled conjunctival allergen challenge (CAC) trials in patients with a history of allergic conjunctivitis. Patients were evaluated with an ocular itching severity score ranging from 0 (no itching) to 4 (incapacitating itch) at several time points after CAC administration.

    — Patients treated with Zerviate demonstrated statistically and clinically significantly less ocular itching vs. vehicle at 15 minutes and 8 hours after treatment.

- Warnings and precautions of Zerviate include contamination of tip and solution and contact lens wear.

- The most common adverse events (1 – 7%) with Zerviate use were ocular hyperemia, instillation site pain, and visual acuity reduced.

- The recommended dose of Zerviate is one drop in each affected eye twice daily (approximately 8 hours apart).

- Nicox's launch plans for Zerviate are pending. Zerviate will be available as a 0.24% ophthalmic solution in 7.5 mL and 10 mL bottles.