Verkazia® (cyclosporine) – New orphan drug approval

- On June 24, 2021, Santen Pharmaceutical announced the FDA approval of Verkazia (cyclosporine) ophthalmic emulsion 0.1%, for the treatment of vernal keratoconjunctivitis (VKC) in children and adults.

- VKC is a rare and recurrent allergic eye condition, mainly occurring in children and adolescents that causes severe inflammation of the surface of the eye.

- Ophthalmic cyclosporine is also available as brand Restasis® 0.05% and Cequa™ 0.09%.

    — Restasis and Cequa are both approved for increased tear production in patients with keratoconjunctivitis sicca (dry eye).

- The efficacy of Verkazia was established in two randomized, double-masked, vehicle-controlled clinical studies (VEKTIS and NOVATIVE). VEKTIS and NOVATIVE enrolled 168 and 118 patients, respectfully. In the VEKTIS study, key efficacy evaluation was based on the change in corneal fluorescein staining (CFS) score and in itching score over 4 months. CFS score was measured using a 5-point scale (0 = no stain, and 5 = more stain). Itching score was measured using a Visual Analogue Scale (0 = no itch to 100 = maximal itch).

    — At 4 months, the mean change in CFS score from baseline was -1.2 with vehicle, -2.3 with Verkazia four times daily, and -1.9 with Verkazia twice daily.
    — At 4 months, the mean change in itching score from baseline was -25.4 with vehicle, -44.1 with Verkazia four times daily, and -35.8 with Verkazia twice daily.
    — Analyses of the CFS score and itching score at month 1 of the efficacy evaluation period in the NOVATIVE Study also provided supporting evidence.

- A warning and precaution for Verkazia is potential for eye injury and contamination.

- The most common adverse reactions with Verkazia use were eye pain and eye pruritis.

- The recommended dose of Verkazia is one drop instilled 4 times daily (morning, noon, afternoon, and evening) into each affected eye.

    — Treatment can be discontinued after signs and symptoms are resolved and can be reinitiated if there is a recurrence.

- Santen Pharmaceutical's launch plans for Verkazia are pending. Verkazia will be available as a 0.1% ophthalmic emulsion