CEQUA™ (cyclosporine) – New drug approval

- On August 16, 2018, Sun Pharma announced the FDA approval of CEQUA (cyclosporine [CsA]), to increase tear production in patients with keratoconjunctivitis sicca (dry eye).

- Dry eye disease occurs when the quantity and/or quality of tears fails to keep the surface of the eye properly lubricated. The disease causes a scratchy sensation or a feeling that something is in the eye. Other symptoms include stinging or burning, episodes of excess tearing following periods of stress, discharge, pain, and redness in the eye.

    - Greater than 16 million patients are affected by dry eye disease in the U.S.

- CEQUA is a calcineurin inhibitor immunosuppressant that provides a nanomicellar formulation of CsA. The small size of the nanomicelles facilitates entry into corneal and conjunctival cells, enabling delivery of high concentrations of CsA.

- CsA is also available as the ophthalmic emulsions Restasis® and Restasis Multidose™.

    - Both Restasis products contain cyclosporine 0.5 mg/mL and are indicated to increase tear production in patients whose tear production is presumed to be suppressed due to ocular inflammation associated with keratoconjunctivitis sicca.

- The efficacy of CEQUA was demonstrated in two vehicle-controlled studies enrolling 1,048 patients with keratoconjunctivitis sicca for 84 days.

    - In the first study, 16.8% of eyes treated with CEQUA vs. 8.6% of eyes treated with vehicle experienced ≥ 10-mm increase in tear production (difference: 8.2% [95% CI: 1.9%, 14.6%]; $p < 0.01$).
    - In the second study, 16.6% of eyes treated with CEQUA vs. 9.2% of eyes treated with vehicle experienced ≥ 10-mm increase in tear production (difference: 7.3% [95% CI: 3.3%, 11.3%]; $p < 0.01$).

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

- The most common adverse reactions with CEQUA use were instillation site pain (22%) and conjunctival hyperemia (6%).

- The recommended dosage of CEQUA is one drop instilled twice daily (approximately 12 hours apart) into each eye.

    - CEQUA can be used concomitantly with artificial tears, allowing a 15-minute interval between products.
    - Discard the vial immediately after using in both eyes.

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- Sun Pharma’s launch plans for CEQUA are pending. CEQUA will be available as a 0.09% ophthalmic solution in preservative-free, single-use vials.