Vevye (cyclosporine) – New drug approval

- On May 30, 2023, the FDA approved Novaliq's Vevye (cyclosporine ophthalmic solution), for the treatment of the signs and symptoms of dry eye disease (DED).

- Other ophthalmic formulations of cyclosporine are available under the brand names Restasis®, Cequa®, and Verkazia®. In addition, generics are available for Restasis.

    - Restasis (and its generics) and Cequa are approved for keratoconjunctivitis sicca (dry eye).
    - Verkazia is approved for vernal keratoconjunctivitis.

- The efficacy of Vevye was established in two randomized, vehicle-controlled studies in 1,369 patients with DED. At day 29 across the two studies, there was a statistically significant higher percentage of eyes with increases of ≥ 10 mm from baseline in Schirmer's wetting. This effect was seen in approximately 10% of Vevye-treated patients vs. approximately 6% of vehicle-treated patients.

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

- The most common adverse reaction with Vevye use was instillation site reactions.

- The recommended dose of Vevye is one drop instilled twice a day in each eye approximately 12 hours apart.

- Novaliq's launch plans for Vevye are pending. Vevye will be available as an ophthalmic solution containing cyclosporine 0.1%.