Khindivi™ (hydrocortisone) – New drug approval

- On May 28, 2025, Eton Pharmaceuticals announced the FDA approval of Khindivi (hydrocortisone), as **replacement therapy in pediatric patients 5 years of age and older with adrenocortical insufficiency**.
    - Khindivi is not approved for increased dosing during periods of stress or acute events. A different hydrocortisone-containing drug product should be used for stress dosing.
- Khindivi is a corticosteroid and the first oral solution formulation of hydrocortisone.
- Warnings and precautions for Khindivi include adrenal crisis; systemic adverse reactions due to inactive ingredients; immunosuppression and increased risk of infection with use of a dosage greater than replacement; growth retardation; Cushing's syndrome due to use of excessive doses of corticosteroids; decrease in bone mineral density; psychiatric adverse reactions; ophthalmic adverse reactions; gastrointestinal adverse reactions; risk of Kaposi's sarcoma with use of a dosage greater than replacement; and vaccination.
- Common adverse reactions for corticosteroids include fluid retention, alteration in glucose tolerance, elevation in blood pressure, behavioral and mood changes, increased appetite, and weight gain.
- The recommended starting replacement dosage of Khindivi is 8 to 10 mg/m^2 daily administered orally with or without food. Higher doses may be needed based on the patient's age and symptoms of the disease. Use of a lower starting dose may be sufficient in patients with residual but decreased endogenous cortisol production.
    - The total daily dose should be divided into 3 doses and administered 3 times daily. Older pediatric patients may have their daily dose divided by 2 and administered twice daily.
    - Refer to the Khindivi drug label for complete dosing and administration recommendations.
- Eton Pharmaceuticals plans to launch Khindivi in the week of June 2nd. Khindivi will be available as a 1 mg/mL oral solution.