Ermeza™ (levothyroxine) – New drug approval

- On April 29, 2022, the FDA approved Mylan's Ermeza (levothyroxine) oral solution, in adult and pediatric patients, including neonates:
    - As a replacement therapy in primary (thyroidal), secondary (pituitary), and tertiary (hypothalamic) congenital or acquired hypothyroidism
    - As an adjunct to surgery and radioiodine therapy in the management of thyrotropin-dependent well-differentiated thyroid cancer.
- Limitations of use for Ermeza include:
    - Not indicated for suppression of benign thyroid nodules and nontoxic diffuse goiter in iodine-sufficient patients as there are no clinical benefits and overtreatment with Ermeza may induce hyperthyroidism.
    - Not indicated for treatment of hypothyroidism during the recovery phase of subacute thyroiditis.
- Levothyroxine is available in various other oral dosage formulations, including generically as a tablet and capsule.
- Ermeza carries a boxed warning that it is not for treatment of obesity or for weight loss.
- Ermeza is contraindicated in patients with:
    - Uncorrected adrenal insufficiency
    - Hypersensitivity to glycerin and edetate disodium, inactive ingredients in Ermeza.
- Warnings and precautions for Ermeza include serious risks related to overtreatment or undertreatment of Ermeza; cardiac adverse reactions in the elderly and in patients with underlying cardiovascular disease; myxedema coma; acute adrenal crisis in patients with concomitant adrenal insufficiency; worsening of diabetic control; and decreased bone mineral density associated with thyroid hormone over replacement.
- Adverse reactions associated with levothyroxine therapy are primarily those of hyperthyroidism due to therapeutic overdosage: arrhythmias, myocardial infarction, dyspnea, muscle spasm, headache, nervousness, irritability, insomnia, tremors, muscle weakness, increased appetite, weight loss, diarrhea, heat intolerance, menstrual irregularities, and skin rash.
- Ermeza is administered orally once daily, preferably on an empty stomach, one-half to one hour before breakfast. For complete dosing and administration recommendations, refer to the drug label.
- Mylan's launch plans for Ermeza are pending. Ermeza will be available as a 150 mcg/5 mL oral solution.