Likmez™ (metronidazole) – New drug approval

- On September 25, 2023, Appili Therapeutics announced the FDA approval of Likmez (metronidazole), for the treatment of:
    - Symptomatic trichomoniasis caused by *Trichomonas vaginalis* in adult females and males when the diagnosis is confirmed by appropriate laboratory procedures
    - Asymptomatic trichomoniasis caused by *Trichomonas vaginalis* in adult females when the organism is associated with endocervicitis, cervicitis, or cervical erosion
    - Acute intestinal amebiasis (amoebic dysentery) and amebic liver abscess in adults and pediatric patients
    - Several other serious infections caused by susceptible anaerobic bacteria in adults. Refer to the drug label for a complete list of indications.
- Likmez is the first FDA approved oral suspension formulation of metronidazole.
    - Other oral formulations of metronidazole include a capsule and a tablet (both available generically) that carry similar indications as Likmez.
- Likmez carries a boxed warning for potential for carcinogenicity.
- Likmez is contraindicated in patients:
    - With prior history of hypersensitivity to metronidazole or other nitroimidazole derivatives
    - Who have used disulfiram within the last two weeks
    - Who consume alcohol or products containing propylene glycol during and for at least three days after Likmez therapy
    - With Cockayne syndrome.
- Additional warnings and precautions for Likmez include central and peripheral nervous system effects, fungal superinfections, blood dyscrasias, and drug-resistant bacteria.
- The most common adverse reactions with Likmez use were nausea, headache, anorexia, vomiting, diarrhea, abdominal cramping, epigastric distress, and constipation.
- The recommended oral dose and duration of treatment with Likmez depends on the indication. Refer to the label for complete dosing and administration recommendations.
- Likmez has been licensed to Saptalis Pharmaceuticals for commercialization in the U.S. and launch plans are pending. Likmez will be available as a 500 mg/5 mL oral suspension.