Trimpex™ (trimethoprim) – New drug approval

- Key Therapeutics received FDA approval of Trimpex (trimethoprim) oral solution, for pediatric patients for the treatment of acute otitis media due to susceptible strains of *Streptococcus pneumoniae* and *Haemophilus influenza*, and for adult patients for the treatment of initial episodes of uncomplicated urinary tract infections due to susceptible strains of the following organisms: *Escherichia coli*, *Proteus mirabilis*, *Klebsiella pneumoniae*, *Enterobacter* species and coagulase-negative *Staphylococcus* species, including *S. saprophyticus*.
    - Trimpex is not indicated for prophylactic or prolonged administration in otitis media at any age.
- Trimethoprim oral solution is also available as Primsol®. Generic trimethoprim tablets are also available.
    - Trimethoprim tablets are indicated for the treatment of initial episodes of uncomplicated urinary tract infections due to susceptible organisms.
- Trimpex is contraindicated in individuals hypersensitive to trimethoprim and in those with documented megaloblastic anemia due to folate deficiency.
- Other warnings and precautions of Trimpex include interference with hematopoiesis; caution in patients with impaired renal or hepatic function; drug interactions; drug/laboratory test interactions; and carcinogenesis, mutagenesis, and impairment of fertility.
- The most common adverse events (> 1%) with Trimpex in pediatric patients are diarrhea, vomiting and rash.
- The recommended dosage of Trimpex for pediatric patients with acute otitis media is 10 mg/kg orally per 24 hours, given in divided doses every 12 hours for 10 days.
- The recommended dosage of Trimpex for adult patients with urinary tract infections is 100 mg (10 mL) orally every 12 hours or 200 mg (20 mL) every 24 hours, each for 10 days.
- Trimpex will be available in pharmacies in about 2 weeks. Trimpex will be available as 50 mg/5 mL bubble gum flavored oral solution.