Xerava™ (eravacycline) – New drug approval

- On August 27, 2018, Tetraphase Pharmaceuticals' announced the FDA approval of Xerava (eravacycline), for the treatment of complicated intra-abdominal infections (cIAI) caused by susceptible microorganisms in patients 18 years of age and older.
    - The susceptible microorganisms include Escherichia coli, Klebsiella pneumoniae, Citrobacter freundii, Enterobacter cloacae, Klebsiella oxytoca, Enterococcus faecalis, Enterococcus faecium, Staphylococcus aureus, Streptococcus anginosus group, Clostridium perfringens, Bacteroides species, and Parabacteroides distasonis.
    - Xerava is not indicated for the treatment of complicated urinary tract infections.
- cIAIs are the second-most prevalent infection site in intensive care units (ICUs) and the second leading cause of infection-related mortality in ICUs.
- Xerava is a novel, fully-synthetic fluorocycline that is structurally similar to the tetracycline-class of antibacterial drugs.
- The efficacy of Xerava was demonstrated in two studies enrolling 1,041 adults hospitalized with cIAI. The studies compared Xerava with either ertapenem or meropenem for 4 to 14 days of therapy. Clinical cure was defined as complete resolution or significant improvement of signs or symptoms of the index infection at the test of cure (TOC) visit which occurred 25 to 31 days after randomization.
    - In study one at TOC, 86.8% of the Xerava patients demonstrated clinical cure vs. 87.6% of ertapenem treated patients (Difference = -0.80 [95% CI: -7.1, 5.5]).
    - In study two at TOC, 90.8% of the Xerava patients demonstrated clinical cure vs. 91.2% of meropenem treated patients (Difference = -0.50 [95% CI: -6.3, 5.3]).
- Warnings and precautions of Xerava include hypersensitivity reactions, tooth discoloration and enamel hypoplasia, inhibition of bone growth, *Clostridium difficile*-associated diarrhea, tetracycline class adverse reactions, potential for microbial overgrowth, and development of drug-resistant bacteria.
- The most common adverse reactions (≥ 3%) with Xerava use were infusion site reactions, nausea, and vomiting.
- The recommended dosage of Xerava is 1 mg/kg by intravenous infusion over approximately 60 minutes every 12 hours for 4 to 14 days.
    - The duration of therapy should be guided by the severity and location of infection and the patient's clinical response.
- The company is aiming for a price range of $175 - $250 per day.
- Tetraphase's plans to launch Xerava in the fourth quarter of 2018. Xerava will be available as a 50 mg preservative-free, lyophilized powder in single-dose vials.