Zinplava™ (bezlotoxumab) – New Drug Approval

- On October 21, 2016, Merck announced the FDA approval of Zinplava (bezlotoxumab) injection, to reduce recurrence of *Clostridium difficile* infection (CDI) in patients 18 years of age or older who are receiving antibacterial drug treatment of CDI and are at a high risk for CDI recurrence.
    - Zinplava is not indicated for the treatment of CDI. Zinplava is not an antibacterial drug and should only be used in conjunction with antibacterial drug treatment of CDI.
- CDI is caused by bacteria that produce toxins, including toxin B. Symptoms of CDI include mild-to-severe diarrhea, abdominal pain, and fever. The incidence of recurrent CDI is higher in certain populations, including people 65 years of age and older and those with compromised immune systems.
- Zinplava is a sterile, preservative-free solution containing bezlotoxumab, a human monoclonal antibody that binds to *C. difficile* toxin B. Binding to toxin B neutralizes its effects.
- The safety and efficacy of Zinplava were evaluated in two placebo-controlled trials in 1,613 adult patients receiving standard of care antibacterial drugs for treatment of CDI. After achieving a clinical cure with antibacterial therapy, patients were evaluated for recurrence of CDI through 12 weeks following administration of Zinplava or placebo.
    - In the first trial, 60.1% of patients in the Zinplava arm achieved a sustained clinical response vs. 55.2% in the placebo arm (95% CI: -2.1, 11.7)
    - In the second trial, 66.8% of patients in the Zinplava arm achieved a sustained clinical response vs. 52.1% in the placebo arm (95%CI: 7.7, 21.4).
- The *Warnings and Precautions* section of Zinplava includes heart failure.
- The most common adverse events (≥ 4%) with Zinplava use were nausea, pyrexia, and headache.
- The recommended dose of Zinplava is a single dose of 10 mg/kg given as an intravenous infusion over 60 minutes.
    - Zinplava should be administered during antibacterial drug treatment for CDI.
    - Zinplava should be administered via a low protein binding 0.2 micron to 5 micron in-line or add-on filter.
    - The safety and efficacy of repeat administration of Zinplava in patients with CDI have not been studied.
- Merck plans to launch Zinplava in the first quarter of 2017. Zinplava will be available as a 1,000 mg/40 mL (25 mg/mL) solution in a single-dose vial.