Vabomere™ (meropenem/vaborbactam) – New drug approval

- On August 29, 2017, the FDA announced the approval of The Medicines Company's Vabomere (meropenem/vaborbactam), for the treatment of patients 18 years of age and older with complicated urinary tract infections (cUTI) including pyelonephritis caused by the following susceptible microorganisms: *Escherichia coli*, *Klebsiella pneumoniae*, and *Enterobacter cloacae species* complex.

- Vabomere contains an antibacterial (meropenem) and a beta-lactamase inhibitor (vaborbactam), which inhibits certain types of resistance mechanisms used by bacteria.

- The safety and efficacy of Vabomere was compared to Zosyn® (piperacillin/tazobactam) in a clinical study of 545 adults with cUTI.

    - At the end of treatment visit, clinical cure or improvement and microbiological eradication were achieved in 98.4% of Vabomere-treated patients vs. 94.3% of Zosyn-treated patients (difference: 4.1%, [95% CI: 0.3, 8.8]).
    - Seven days after completion of treatment, clinical cure and microbiological eradication were demonstrated in 76.5% of Vabomere-treated patients vs. 73.2% of Zosyn-treated patients (difference: 3.3%, [95% CI: -6.2, 13]).

- Vabomere is contraindicated in patients with known hypersensitivity to any component of Vabomere or to other drugs in the same class, or in patients who have demonstrated anaphylactic reactions to beta-lactam antibacterial drugs.

- Warnings and precautions for Vabomere include hypersensitivity reactions, seizure potential, *Clostridium difficile*-associated diarrhea, risk of breakthrough seizures due to drug interaction with valproic acid, thrombocytopenia, potential for neuromotor impairment, development of drug resistant bacteria, and overgrowth of nonsusceptible organisms.

- The most common adverse reactions (≥ 3%) with Vabomere use were headache, phlebitis/infusion site reactions, and diarrhea.

- The recommended dose of Vabomere is 4 grams (2 grams of meropenem and 2 grams of vaborbactam) given intravenously every 8 hours in patients ≥ 18 years of age with an estimated glomerular filtration rate ≥ 50 mL/min/1.73m^2. The duration of treatment is for up to 14 days.

- The Medicines Company plans to launch Vabomere in the 4th quarter of 2017. Vabomere will be available in single-dose vials containing 1 gram of meropenem (equivalent to 1.14 grams of meropenem trihydrate) and 1 gram of vaborbactam.