Recarbrio® (imipenem/cilastatin/relebactam) – New indication

- On June 4, 2020, the FDA announced the approval of Merck's Recarbrio (imipenem/cilastatin/relebactam), for the treatment of patients 18 years of age and older with hospital-acquired bacterial pneumonia and ventilator-associated bacterial pneumonia (HABP/VABP), caused by the following susceptible gram-negative microorganisms: *Acinetobacter calcoaceticus-baumannii* complex, *Enterobacter cloacae, Escherichia coli, Haemophilus influenzae, Klebsiella aerogenes, Klebsiella oxytoca, Klebsiella pneumoniae, Pseudomonas aeruginosa,* and *Serratia marcescens.*

- Recarbrio is also approved for the treatment of complicated urinary tract infections, including pyelonephritis, and complicated intra-abdominal infections.

- HABP and VABP are a type of pneumonia that occurs in hospitalized patients and can cause symptoms such as fever, chills, cough, chest pain and increased oxygen requirements.

- The approval of Recarbrio for the new indication was based on a randomized, double-blind study in 535 hospitalized adults with HABP/VABP. Patients were randomized to Recarbrio or piperacillin/tazobactam (eg, Zosyn®) for 7 to 14 days of therapy. The modified intent-to-treat (mITT) population included 531 randomized patients who received at least one dose of trial treatment and did not have only gram-positive cocci on Gram stain of the baseline lower respiratory tract specimen. Efficacy outcomes included incidence of all-cause mortality through day 28 and clinical response at the early follow-up (EFU) visit (7 to 14 days after the end of therapy) in the mITT population.

    — All-cause mortality was 15.9% in patients who received Recarbrio and 21.3% in patients who received piperacillin/tazobactam through day 28 of the study (treatment difference: -5.3; 95% CI: -11.9, 1.2).
    — Clinical response at the EFU visit was achieved in 61.0% of patients receiving Recarbrio and 55.8% of patients receiving piperacillin/tazobactam (treatment difference: 5.0; 95% CI: -3.2, 13.2).

- The most common adverse reactions (≥ 5%) with Recarbrio use for the treatment of HABP/VABP were increased alanine aminotransferase, increased aspartate aminotransferase, anemia, diarrhea, hypokalemia, and hyponatremia.

- The recommended dose of Recarbrio for all its indications is 1.25 grams (imipenem 500 mg/ cilastatin 500 mg/relebactam 250 mg) administered by intravenous infusion over 30 minutes every 6 hours in patients 18 years of age and older with creatinine clearance of 90 mL/min or greater.

    — The severity and location of infection, as well as clinical response should guide the duration of therapy. The recommended duration of treatment with Recarbrio is 4 days to 14 days.