Recarbrio OK'd for complicated urinary tract, intra-abdominal infections

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(HealthDay)—The antibacterial drug product Recarbrio (imipenem, cilastatin, and relebactam) has been approved to treat complicated urinary tract infections (cUTI) and complicated intra-abdominal infections (cIAI) in adults, the U.S. Food and Drug Administration announced.

Recarbrio, a three-drug combination injection, is intended to be used for patients who have limited or no alternative antibacterial drugs to treat their infection, Ed Cox, M.D., M.P.H., director for the Office of Antimicrobial Products in the FDA Center for Drug Evaluation and Research, noted in an FDA release. The recommended dose is 1.25 g administered by intravenous infusion for 30 minutes every six hours in patients aged 18 years or older with creatinine clearance of at least 90 mL/minute.

Approval was partly based on data showing the efficacy and safety of imipenem-cilastatin, which has been previously approved by the FDA, in treating cUTI and cIAI, as well as data from in vitro studies and animal models of infection evaluating the efficacy of relebactam. Two trials assessed the safety of Recarbrio: one study of 298 adults with cUTI, 99 of whom were treated with the proposed dose of Recarbrio, and one study of 347 adults with cIAI, 117 of whom were treated with Recarbrio.

The most commonly reported adverse reactions were nausea, diarrhea, headache, fever, and increased liver enzymes. The FDA notes that Recarbrio is not indicated for patients taking ganciclovir because generalized seizures have been reported in this population. Recarbrio use should also be avoided for patients taking valproic acid or divalproex sodium.

Approval was granted to Merck & Co.

More information: More Information