Recarbrio (imipenem, cilastatin and relebactam)

FDA approves new treatment for complicated urinary tract and complicated intra-abdominal infections

Silver Spring, MD, USA (July 17, 2019) -- The U.S. Food and Drug Administration has approved Recarbrio (imipenem, cilastatin and relebactam), an antibacterial drug product to treat adults with complicated urinary tract infections (cUTI) and complicated intra-abdominal infections (cIAI).

“The FDA remains focused on facilitating the development of safe and effective new antibacterial drugs to give patients more options to fight serious infections,” said Ed Cox, M.D., M.P.H., director for the Office of Antimicrobial Products in FDA’s Center for Drug Evaluation and Research. “It is important that the use of Recarbrio be reserved for situations when there are limited or no alternative antibacterial drugs for treating a patient’s infection.”

Recarbrio is a three-drug combination injection containing imipenem-cilastatin, a previously FDA-approved antibiotic, and relebactam, a new beta-lactamase inhibitor.

The determination of efficacy of Recarbrio was supported in part by the findings of the efficacy and safety of imipenem-cilastatin for the treatment of cUTI and cIAI. The contribution of relebactam to Recarbrio was assessed based on data from in vitro studies and animal models of infection. The safety of Recarbrio, administered via injection, was studied in two trials, one each for cUTI and cIAI. The cUTI trial included 298 adult patients with 99 treated with the proposed dose of Recarbrio. The cIAI trial included 347 patients with 117 treated with the proposed dose of Recarbrio.

The most common adverse reactions observed in patients treated with Recarbrio included nausea, diarrhea, headache, fever and increased liver enzymes.

Recarbrio should not be used in patients taking ganciclovir unless the benefits outweigh the risks as generalized seizures have been reported. Patients should also avoid using Recarbrio when taking valproic acid or divalproex sodium, drugs used to manage seizures, as a reduction in valproic acid level may lead to seizures.

Recarbrio received FDA’s Qualified Infectious Disease Product (QIDP)

designation. The QIDP designation is given to antibacterial and antifungal drug products intended to treat serious or life-threatening infections under the Generating Antibiotic Incentives Now (GAIN) title of the FDA Safety and Innovation Act. As part of QIDP designation, Recarbrio was granted Priority Review under which the FDA's goal is to take action on an application within an expedited time frame.

The FDA granted the approval of Recarbrio for the treatment to Merck & Co., Inc.

A key global challenge the FDA faces as a public health agency is addressing the threat of antimicrobial-resistant infections. Among the FDA's other efforts to address antimicrobial resistance, is the focus on facilitating the development of safe and effective new treatments to give patients more options to fight serious infections.

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

U.S. Food and Drug Administration, 17.07.2019 (tB).