



FDA Advisory Committee Provides Opinion of DORIBAX(TM) for the Treatment of Hospital-Acquired Pneumonia

RARITAN, N.J., July 16, 2008 /PRNewswire via COMTEX News Network/ -- Johnson & Johnson Pharmaceutical Research & Development, L.L.C. announced today that the U.S. Food and Drug Administration's (FDA) Anti-Infective Drugs Advisory Committee voted in favor of the efficacy and safety data for DORIBAX(TM) (doripenem for injection) for the treatment of hospital-acquired pneumonia, or nosocomial pneumonia (NP), and ventilator-associated pneumonia (VAP).

The committee voted that 500 mg of DORIBAX at both the one-hour and four-hour infusion regimens was safe (8-5) and effective (7-6). The committee did not agree on the appropriate non-inferiority margins for anti-infectives trials in nosocomial pneumonia.

The independent Advisory Committee provides recommendations based on its evaluation of the information presented. However, the final decision regarding approval of the drug is made by the FDA.

"We recognize that there is an important need for new antibiotics to treat these serious hospital infections," said Joanne Waldstreicher, M.D., Global Head, Drug Development, Johnson & Johnson Pharmaceutical Research & Development, L.L.C. "We look forward to further discussions with the FDA as they complete their review of DORIBAX for the treatment of hospital-acquired and ventilator-associated pneumonia."

DORIBAX is an intravenous (IV) antibiotic for hospital use, and belongs to a class of antibacterial drugs called carbapenems. Carbapenems are important antibiotics to treat serious -- and sometimes life-threatening -- infections caused by a broad range of bacteria, which are characterized as Gram-negative and Gram-positive, based on a classification process that is used to identify the specific type of bacteria.

DORIBAX is approved in the U.S. for the treatment of complicated intra-abdominal infections (cIAI) and complicated urinary tract infections (cUTI), including pyelonephritis, due to susceptible bacteria, and is marketed by Ortho-McNeil, Division of Ortho-McNeil-Janssen Pharmaceuticals, Inc. The use of DORIBAX for the treatment of NP, including VAP, is under regulatory review in the U.S. DORIBAX received a positive opinion from the Committee for Medicinal Products for Human Use (CHMP) and is awaiting final approval in Europe for cIAI, cUTI and NP, including VAP. Doripenem is licensed from Shionogi & Co., Ltd.

INDICATIONS

DORIBAX is indicated as a single agent for the treatment of: complicated intra-abdominal infections caused by susceptible strains of *E. coli*, *K. pneumoniae*, *P. aeruginosa*, *B. caccae*, *B. fragilis*, *B. thetaiotaomicron*, *B. uniformis*, *B. vulgatus*, *S. intermedius*, *S. constellatus* or *P. micros*, and for the treatment of complicated urinary tract infections, including pyelonephritis, caused by susceptible strains of *E. coli*, including cases with concurrent bacteremia, *K. pneumoniae*, *P. mirabilis*, *P. aeruginosa*, or *A. baumannii*.

To reduce the development of drug-resistant bacteria and maintain the effectiveness of DORIBAX and other antibacterial drugs, DORIBAX should be used only to treat infections that are proven or strongly suspected to be caused by susceptible bacteria. When culture and susceptibility information are available, they should be considered in selecting and modifying antibacterial therapy. In the absence of such data, local epidemiology and susceptibility patterns may contribute to the empiric selection of therapy.

IMPORTANT SAFETY INFORMATION

DORIBAX is contraindicated in patients with known serious hypersensitivity to doripenem or other carbapenems or in patients who have demonstrated anaphylactic reactions to beta-lactams.

Serious and occasionally fatal hypersensitivity (anaphylactic) and serious skin reactions have been reported in patients receiving beta-lactam antibiotics. These reactions are more likely to occur in individuals with a history of sensitivity to multiple allergens. If an allergic reaction to DORIBAX occurs, discontinue the drug. Serious acute anaphylactic reactions require emergency treatment with epinephrine and other emergency measures, including oxygen, IV fluids, IV antihistamines, corticosteroids, pressor amines and airway management, as clinically indicated.

Carbapenems may reduce serum valproic acid concentrations to subtherapeutic levels, resulting in loss of seizure control. Serum valproic acid concentrations should be monitored frequently after initiating carbapenem therapy. Alternative

antibacterial or anticonvulsant therapy should be considered if serum valproic acid concentrations cannot be maintained in the therapeutic range or seizures occur.

Clostridium difficile-associated diarrhea (CDAD) has been reported with use of nearly all antibacterial agents and may range in severity from mild diarrhea to fatal colitis. CDAD must be considered in all patients who present with diarrhea following antibiotic use. Careful medical history is necessary since CDAD has been reported to occur over two (2) months after administration of antibacterial agents. If CDAD is suspected or confirmed, ongoing antibiotic use not directed against C. difficile may need to be discontinued.

When DORIBAX has been used investigationally via inhalation, pneumonitis has occurred. DORIBAX should not be administered by this route.

Safety and effectiveness in pediatric patients have not been established.

The most common adverse reactions (greater than or equal to 5%) observed in clinical trials were headache, nausea, diarrhea, rash and phlebitis.

Please see the DORIBAX Full Prescribing Information by visiting www.DORIBAX.com

Ortho-McNeil, Division of Ortho-McNeil-Janssen Pharmaceuticals, Inc., is committed to providing innovative, high-quality, prescription medicines and resources in the areas of bacterial infection and cardiovascular disease for healthcare providers and their patients in hospitals and other care facilities. For more information, visit www.ortho-mcneil.com.

Johnson & Johnson Pharmaceutical Research & Development, L.L.C. (J&JPRD) is headquartered in Raritan, NJ, and has facilities throughout Asia, Europe and the United States. J&JPRD is leveraging drug discovery and drug development in a variety of therapeutic areas to address unmet medical needs worldwide.

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