



Johnson & Johnson
PHARMACEUTICAL RESEARCH
& DEVELOPMENT, L.L.C.

FOR IMMEDIATE RELEASE

**FDA REQUIRES ADDITIONAL INFORMATION ON DORIBAX FOR TREATMENT OF
HOSPITAL-ACQUIRED PNEUMONIA**

Raritan, NJ August 21, 2008 – Johnson & Johnson Pharmaceutical Research & Development, L.L.C. (J&JPRD) today announced that the U.S. Food and Drug Administration (FDA) requires additional information before it will approve the company's New Drug Application (NDA) for DORIBAX™ (doripenem for injection) for the treatment of hospital-acquired pneumonia, also known as nosocomial pneumonia (NP), including ventilator-associated pneumonia (VAP).

In response to the J&JPRD application seeking approval for DORIBAX for the additional indication of the treatment of NP, including VAP, the FDA issued a Complete Response letter outlining the actions necessary to address outstanding issues.

J&JPRD is reviewing the agency's letter and will work to resolve any outstanding questions. The NDA for DORIBAX for the treatment of NP, including VAP, was submitted to the FDA in June 2007.

The NDA for DORIBAX for the treatment of NP, including VAP, was the subject of a July 16, 2008 U.S. Food and Drug Administration Anti-Infective Drugs Advisory Committee. Based on data presented from two large, nosocomial pneumonia trials, the committee voted that 500 mg of DORIBAX at both the one-hour and four-hour infusion regimens were safe (8-5) and effective (7-6) in the treatment of NP, including VAP. The committee did not agree that the non-inferiority margin for the DORIBAX NP trials was appropriately justified, nor did it agree on the appropriate margin for NP trials in general. J&JPRD is confident in the NP data submitted and will work with the FDA to address the issues raised in the Complete Response letter.

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 was approved in the U.S. in October 2007 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. DORIBAX also is approved in Europe and Russia 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 ($\geq 5\%$) 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., is part of Johnson & Johnson, the world's most broadly based producer of healthcare products. J&JPRD is headquartered in Raritan, NJ, and has facilities throughout Asia, Europe and the U.S. J&JPRD is leveraging drug discovery and drug development in a variety of therapeutic areas to address unmet medical needs worldwide.

FORWARD LOOKING STATEMENT

(This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995. These statements are based on current expectations of future events. If underlying assumptions prove inaccurate or unknown risks or uncertainties materialize, actual results could vary materially from the Company's expectations and projections. Risks and uncertainties include general industry conditions and competition; economic conditions, such as interest rate and currency exchange rate fluctuations; technological advances and patents attained by competitors; challenges inherent in new product development, including obtaining regulatory approvals; domestic and foreign health care reforms and governmental laws and regulations; and trends toward health care cost containment. A further list and description of these risks, uncertainties and other factors can be found in Exhibit 99 of Johnson & Johnson's Annual Report on Form 10-K for the fiscal year ended December 30, 2007. Copies of this Form 10-K, as well as subsequent filings, are available online at www.sec.gov <<http://www.sec.gov>>, www.jnj.com <<http://www.jnj.com>> or on request from Johnson & Johnson. The Company does not undertake to update any forward-looking statements as a result of new information or future events or developments.)

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