1000 US Highway 202 South
Raritan, NJ 08869

January 3, 2012

Dear Healthcare Professional:

Janssen Pharmaceuticals, Inc. wishes to inform you of a prospective, randomized, double-blind, double-dummy, multicenter Phase 3 study of an investigational use of DORIBAX® (doripenem) in ventilator-associated pneumonia (VAP) that was prematurely terminated when interim analyses of data from 274 of the planned 524 subjects showed a **numerically higher mortality rate and a numerically lower clinical cure rate among subjects treated with a fixed 7-day course of 1 gram q8h DORIBAX® compared with those treated with a fixed 10-day course of imipenem-cilastatin.** DORIBAX® is not approved for nosocomial pneumonia, including VAP, nor is it approved for this dose and dosing regimen. DORIBAX® is approved for the treatment of adults with complicated Intra-Abdominal Infections (cIAI) and complicated Urinary Tract Infections (cUTI), including pyelonephritis.

The study was designed to assess the efficacy and safety of a fixed 7-day course of doripenem (1g, 4-hour infusion, q8h) compared with a fixed 10-day course of imipenem-cilastatin (1g, 1 hour infusion, q8h) as treatment for adult subjects hospitalized for at least 5 days and diagnosed with VAP. The primary objective of the study was to demonstrate the noninferiority of doripenem to imipenem-cilastatin in the Microbiological Intent-to-Treat (MITT) population and the Microbiologically Evaluable (ME) population.

Table 1 below shows the interim results for both clinical cure rates and 28-day all-cause mortality rates for the MITT and ME analysis populations.

Table 1. Summary of Clinical Cure Rates and All-Cause 28-Day Mortality Rates

Analysis Population	Doripenem Group Fixed 7-day Course %	Imipenem Group Fixed 10-day Course %	Difference %	2-sided 95% CI %
Clinical Cure Rates				
MITT	45.6	56.8	-11.2	-26.3 to 3.8
ME	49.1	66.1	-17	-34.7 to 0.8
Creatinine Clearance* (MITT)				
≥ 150 mL/min	44.4	71.4	-27	-55.4 to 1.4
< 150 mL/min	45.9	50	-4.1	-21.9 to 13.7
All Cause 28-day Mortality (MITT)	21.5	14.8	6.7	-5.0 to 18.5

*Calculated using the Cockcroft and Gault formulas relating serum creatinine with age (in years) and body weight (in kg).

Janssen Pharmaceuticals, Inc., is committed to ensuring that DORIBAX® is used safely and effectively. A copy of the prescribing information for DORIBAX® is enclosed. Should you have any questions

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or require further information regarding the use of DORIBAX® (doripenem), please contact the Janssen Medical Information Center at 1-800-JANSSEN (1-800-526-7736) or online at www.janssenmedinfo.com.

Healthcare professionals should report any serious adverse events suspected to be associated with the use of DORIBAX® to Janssen at 1-800-526-7736. Serious adverse event information may also be reported directly to the FDA's MedWatch reporting system by phone (1-800-FDA-1088), by facsimile (1-800-FDA-0178), online at (https://www.accessdata.fda.gov/scripts/medwatch/medwatch-online.htm), or mailed, using Form FDA 3500, to: MEDWATCH, The FDA Safety Information and Adverse Event Reporting System, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20852-9787.

Sincerely,

Paul Chang, MD
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Janssen Scientific Affairs, LLC

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Janssen
PHARMACEUTICAL COMPANIES
OF Johnson&Johnson