

FDA Issues Complete Response Letter for Ceftobiprole for Treatment of Complicated Skin Infections

RARITAN, N.J., Nov. 26 /PRNewswire/ -- Johnson & Johnson Pharmaceutical Research & Development, L.L.C. (J&JPRD), today announced that it received a Complete Response letter from the U.S. Food and Drug Administration (FDA) regarding its New Drug Application (NDA) for ceftobiprole for the treatment of complicated skin and skin structure infections, including diabetic foot infections.

The FDA has indicated that they cannot approve the NDA for ceftobiprole at this time. They have asked J&JPRD to conduct additional audit work of clinical investigator sites and to address specific questions related to site monitoring.

J&JPRD and its co-development partner, Swiss-based Basilea Pharmaceutica Ltd., are reviewing the Complete Response letter and will continue to work with the FDA to resolve questions that are outlined in the Complete Response letter.

The NDA for ceftobiprole was submitted to the FDA in May 2007, and, in March 2008, J&JPRD received an Approvable Letter regarding the ceftobiprole filing. J&JPRD responded to the FDA's Approvable Letter in August 2008.

Ceftobiprole was approved earlier this year in Canada, and most recently it was approved in Switzerland. Last week, the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency recommended approval of ceftobiprole in the European Union for the treatment of complicated skin and soft tissue infections.

Ceftobiprole is a novel, broad-spectrum, anti-MRSA cephalosporin with activity against methicillin-resistant *Staphylococcus aureus* (MRSA), penicillin-resistant *Streptococcus pneumoniae* and many clinically important Gram-negative bacteria, including *Pseudomonas*.

MRSA is a type of bacteria that is resistant to certain antibiotics. These antibiotics include methicillin and other more common antibiotics such as oxacillin, penicillin and amoxicillin. Staphylococcal (frequently called "Staph") infections, including MRSA, previously occurred most frequently among persons in hospitals and healthcare

facilities who have weakened immune systems. Increasingly, cases are being reported in outpatient and community settings. These cases are referred to as community-associated MRSA (CA-MRSA) and are a growing healthcare concern.

**Johnson & Johnson Pharmaceutical Research & Development,
L.L.C. (J&JPRD)**

J&JPRD 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 United States. J&JPRD is leveraging drug discovery and drug development in a variety of therapeutic areas to address unmet medical needs worldwide.

[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 Johnson & Johnson'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 the Company'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, www.jnj.com or on request from Johnson & Johnson. Johnson & Johnson does not undertake to update any forward-looking statements as a result of new information or future events or developments.]

CONTACTS:

Media: Greg Panico, 908-927-3715 (office) or 908-240-2011 (cell)

Investor Relations: Stan Panasewicz, 732-524-2524 or Tina Pinto, 732-524-2034