



## FDA Issues Complete Response Letter for Ceftobiprole

RARITAN, N.J., Dec 30, 2009 /PRNewswire via COMTEX News Network/ -- Johnson & Johnson Pharmaceutical Research & Development, L.L.C. (J&JPRD) today announced it received a Complete Response letter from the U.S. Food and Drug Administration (FDA) for ceftobiprole. The New Drug Application (NDA) was originally submitted to the FDA in May 2007 for the treatment of complicated skin and skin structure infections (cSSSI), including diabetic foot infections.

The FDA has requested additional information and recommended additional clinical studies be conducted in order to consider a future approval of ceftobiprole in this indication. J&JPRD intends to discuss the best path forward with the FDA as soon as possible.

Ceftobiprole was licensed from Swiss-based Basilea Pharmaceutica Ltd. in February 2005. 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. In November 2008, J&JPRD received a Complete Response letter, which recommended additional site audits be conducted. The Company completed those audits through a third party and included the results in its June 2009 response to the FDA's Complete Response letter.

### *About Ceftobiprole*

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*.

The regulatory review process is ongoing in Europe and other countries for the use of ceftobiprole in adults for the treatment of complicated skin and skin structure infections. Ceftobiprole is approved in Canada, Switzerland, Russia, Azerbaijan, Ukraine and Hong Kong.

### *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 J&JPRD or 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 Johnson & Johnson's Annual Report on Form 10-K for the fiscal year ended December 31, 2008. 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. Neither J&JPRD nor Johnson & Johnson undertakes to update any forward-looking statements as a result of new information or future events or developments.]*

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