

## **New Antibiotic Against Serious Infections – Receives First Approval in Europe**

### **ZEVTERA™ A Broad-spectrum, Anti-MRSA Cephalosporin Antibiotic to Treat Complicated Skin and Soft Tissue Infections Approved in Switzerland**

**Switzerland, 13 November, 2008** – Swissmedic, the Swiss agency for therapeutic products, has approved ZEVTERA™ (ceftobiprole medocartil) for the treatment of complicated skin and soft tissue infections, including diabetic foot infections which have not spread to the bone.

Ceftobiprole is licensed from and co-developed with Basilea Pharmaceutica Ltd.

Janssen-Cilag will market ceftobiprole in Switzerland under the trade name ZEVTERA™. Swiss based Basilea Pharmaceutica Ltd will co-promote the drug in key European markets and North America.

Ceftobiprole is the first, broad-spectrum, anti-MRSA cephalosporin antibiotic with activity against a range of difficult-to-treat Gram-positive and Gram-negative hospital- and community-acquired pathogens including methicillin-resistant *Staphylococcus aureus* (MRSA) and *Pseudomonas aeruginosa*<sup>1</sup>. In clinical trials, ceftobiprole has demonstrated high cure rates in patients with complicated skin infections, including those caused by the potentially deadly MRSA.

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<sup>1</sup> *Pseudomonas aeruginosa*, a gram-negative pathogen, causes a variety of infectious diseases and is the most significant cause of hospital acquired infections particularly in pre-disposed patients with metabolic, haematologic, and malignant diseases.

Data from the European Antimicrobial Resistance Surveillance System (EARSS) show that the prevalence of MRSA - a difficult to treat cause of hospital-and-community acquired infections - while varying considerably among countries, has been rising across Europe for the past six years<sup>2</sup>

The use of ceftobiprole in adults for the treatment of complicated soft tissue infections, including diabetic foot infections which have not spread to the bone, is under regulatory review in United States, Australia and in the European Union among other countries. In Canada, ceftobiprole was approved and launched in August 2008 under the trade name ZEFTERA.

### **About Complicated Skin Infections**

Complicated skin and soft tissue infections are among the most common infections in the hospital setting. *Staphylococcus aureus* is the predominant pathogen in these infections. In recent years, resistant strains, such as MRSA have become increasingly common and have been associated with increased morbidity and mortality. New broad-spectrum antibiotics that cover resistant bacteria such as MRSA, but also clinically important and problematic Gram-negative pathogens, address a high-unmet medical need in the treatment of severe skin and soft tissue infections.

Patients with chronic wounds or those who have recently received antibiotics may also be infected by Gram-negative pathogens. This is frequently the case for diabetic patients with foot infections. Adequate treatment of diabetic foot infections can require hospitalization, surgery and broad-spectrum intravenous antibiotics.

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<sup>2</sup> European Antimicrobial Resistance Surveillance System (EARSS) 2005 Annual Report. Available at: <http://www.rivm.nl/en/>



## About Ceftobiprole

Ceftobiprole, the first anti-MRSA cephalosporin to be approved, is an intravenous antibiotic that belongs to the class of antibacterial drugs known as cephalosporins, which are used to treat serious infections caused by a broad range of bacteria, characterized as Gram-negative and Gram-positive, based on a classification process that is used to identify the specific type of bacteria.

Phase III clinical trials have demonstrated that ceftobiprole is clinically efficacious against the following pathogens: *Enterobacter cloacae*, *Enterococcus faecalis*, *Proteus mirabilis*, *Staphylococcus aureus*, *Staphylococcus epidermidis*, *Streptococcus agalactiae*, *Streptococcus pyogenes*, *Escherichia coli*, *Klebsiella pneumonia* and *Pseudomonas aeruginosa*.

The Janssen-Cilag companies have a long and successful track record in developing and marketing treatments for a wide variety of conditions such as infectious disease, HIV, pain management, fungal infections, multiple myeloma, gastroenterological disorders, epilepsy, Alzheimer's disease, schizophrenia, acute bipolar mania, behavioural psychological symptoms of dementia, disruptive behaviour disorders, and autism. More information can be found at [www.janssen-cilag.com](http://www.janssen-cilag.com). The Janssen-Cilag companies are part of the Johnson & Johnson family of companies.

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 Janssen-Cilag'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. Janssen-Cilag does not undertake to update any forward-looking statements as a result of new information or future events or developments.

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