EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

19 May 2011
EMA/CHMP/399709/2011
Committee for medicinal products for human use (CHMP)

Summary of opinion[1] (initial authorisation)

Vibativ

telavancin

On 19 May 2011 the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for Vibativ, 250 mg, 750 mg powder for concentrate for solution for infusion for the treatment of adults with nosocomial pneumonia (NP) including ventilator associated pneumonia, known or suspected to be caused by methicillin-resistant *Staphylococcus aureus* (MRSA). Vibativ should be used only in situations where it is known or suspected that other alternatives are not suitable. The applicant for this medicinal product is Astellas Pharma Europe B.V. They may request a re-examination of any CHMP opinion, provided they notify the European Medicines Agency in writing of their intention within 15 days of receipt of the opinion.

The active substance of Vibativ is telavancin, a glycopeptide antibacterial, (ATC code: J01XA03). As a semi-synthetic derivative of vancomycin, it inhibits cell wall biosynthesis but also binds to bacterial membranes, causing an increase in membrane permeability that results in inhibition of protein, RNA, and lipid synthesis.

The benefits with VIBATIV result from its ability to exert concentration-dependent bactericidal activity against susceptible Gram-positive bacteria. Telavancin demonstrated efficacy against methicillin susceptible *Staphylococcus aureus* (MSSA) and MRSA in two randomized controlled studies in patients with NP, including ventilator associated pneumonia. The most common side effects observed were fungal infection, insomnia, dysgeusia, headache, dizziness, nausea, constipation, diarrhoea, vomiting, alanine aminotransferase increased, aspartate aminotransferase increased, pruritus, rash, acute renal failure, increased blood creatinine, urine abnormality (foamy urine), fatigue and chills. In particular, acute renal failure remains an important concern, prompting a restricted indication.

A pharmacovigilance plan for Vibativ will be implemented as part of the marketing authorisation.

[1] Summaries of positive opinion are published without prejudice to the commission decision, which will normally be issued 67 days from adoption of the opinion.

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The approved indication is:

“Vibativ is indicated for the treatment of adults with nosocomial pneumonia (NP) including ventilator associated pneumonia, known or suspected to be caused by methicillin-resistant Staphylococcus aureus (MRSA).

VIBATIV should be used only in situations where it is known or suspected that other alternatives are not suitable (see sections 4.3, 4.4, 4.8 and 5.1).

Consideration should be given to official guidance on the appropriate use of antibacterial agents.”

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR), and will be available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

The CHMP, on the basis of quality, safety and efficacy data submitted, considers there to be a favourable benefit to risk balance for Vibativ and therefore recommends the granting of the marketing authorisation.