18 December 2014
EMA/CHMP/757915/2014
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Xydalba

dalbavancin

On 18 December 2014, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Xydalba, 500mg, powder for concentrate for solution for infusion intended for treatment of acute bacterial skin and skin structure infections (ABSSSI) in adults. The applicant for this medicinal product is Durata Therapeutics International 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 Xydalba is dalbavancin, a glycopeptide antibacterial (J01XA04), which interrupts cell wall synthesis in susceptible Gram-positive bacteria.

The benefits with Xydalba are its ability to be active against important groups of Gram-positive bacteria, including strains of methicillin resistant *Staphylococcus aureus* (MRSA) and some *S. aureus* with reduced susceptibility to glycopeptides (GISA), as well as pathogenic streptococci. In addition, it possesses a pharmacokinetic (PK) profile which allows once-weekly intravenous (IV) dosing. The most common side effects are nausea, diarrhoea and headache.

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

The approved indication is:

"Xydalba is indicated for the treatment of acute bacterial skin and skin structure infections (ABSSSI) in adults.

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 made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

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