22 January 2015
EMA/CHMP/803701/2014 - correction
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Orbactiv

oritavancin

On 22 January 2015, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Orbactiv, 400 mg, powder for concentrate for solution for infusion, intended for the treatment of acute bacterial skin and skin structure infections (ABSSSI) in adults.

The applicant for this medicinal product is The Medicines Company UK Ltd. 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 Orbactiv is oritavancin, a glycopeptide antibacterial (J01XA05), acting by inhibition of bacterial cell wall biosynthesis and disruption of bacterial membrane integrity, leading to rapid cell death.

The benefits with Orbactiv are its ability to effectuate cure of ABSSSI with a single intravenous (IV) dose. In two identical designed pivotal trials (SOLO 1 and SOLO 2), oritavancin showed non-inferiority versus vancomycin comparator, for early clinical response (cessation of spread or reduction in size of the lesion) and clinical cure rates. The most common side effects are nausea, hypersensitivity reactions, infusion site reactions, and headache.

A pharmacovigilance plan for Orbactiv will be implemented as part of the marketing authorisation. The approved indication is:

"Orbactiv is indicated for the treatment of acute bacterial skin and skin structure infections (ABSSSI) in adults. (see sections 4.4 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

[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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made 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 Orbactiv and therefore recommends the granting of the marketing authorisation.