EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

21 November 2013
EMA/CHMP/713909/2013
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Deltyba

delamanid

On 21 November 2013, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a conditional marketing authorisation for the medicinal product Deltyba, 50 mg, film-coated tablet intended for the treatment of multi-drug resistant tuberculosis (MDR-TB). Deltyba was designated as an orphan medicinal product on 1 February 2008. The applicant for this medicinal product is Otsuka Novel Products GmbH.

The active substance of Deltyba is delamanid, an antimycobacterial (J04AK06). It exerts its activity by inhibiting the synthesis of the mycobacterial cell wall components, methoxy-mycolic and keto-mycolic acid.

The benefits with Deltyba are based on short term clinical trial data showing that when delamanid was used in combination with an optimal background regimen (OBR) of other anti-tuberculosis medicines in the treatment of pulmonary MDR-TB, it provided a superior outcome over placebo with OBR in terms of sputum culture conversion. Although not able to precisely predict final disease outcome, these data were considered as important demonstration of antitubercular activity within the context of a conditional marketing authorisation recommendation. More definitive data will become available within a short timeframe. The safety database is limited, but the most important side effects noted to date are ECG changes (QTc interval prolongation) and abnormal hepatic function.

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

The approved indication is: “Deltyba is indicated for use as part of an appropriate combination regimen for pulmonary multi-drug resistant tubercolosis (MDR-TB) in adult patients when an effective treatment regimen cannot otherwise be composed for reasons of resistance or tolerability (see sections 4.2, 4.4 and 5.1).

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

[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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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.

The CHMP, on the basis of quality, safety and efficacy data submitted, considers there to be a favourable benefit-to-risk balance for Deltyba and therefore recommends the granting of the marketing authorisation. The marketing authorisation is conditional[2].

[2] A conditional marketing authorisation is granted to a medicinal product that fulfils an unmet medical need when the benefit to public health of immediate availability outweighs the risk inherent in the fact that additional data are still required. The marketing authorisation holder is likely to provide comprehensive clinical data at a later stage.