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Committee for Medicinal Products for Human Use (CHMP)

Zytiga

Scientific conclusions and grounds recommending the variation to the terms of the marketing authorisation

International non-proprietary name: abiraterone

Procedure No. EMEA/H/C/002321/PSUV/0017

Period covered by the PSUR: 28 October 2012 – 27 April 2013

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Scientific conclusions

Taking into account the PRAC Assessment Report on the PSUR for Zytiga, the scientific conclusions of PRAC are as follows:

The clinical trial data provided by MAH showed an imbalance between abiraterone group and placebo group for sepsis-related adverse events that remained after standardising the difference in treatment duration based on event rate per 100 patient-years of exposure. Data from combined study data showed incidence of sepsis 2.7% in the abiraterone group vs. 1.8% in the placebo group, mainly attributable to study COU-AA-301 (4.2% abiraterone group vs. 1.6% placebo group). From post-marketing data sources, a total of 10 cases of non-Urinary Tract Infection reporting sepsis (4 cases), pneumonia (4 cases), lung infection, and septic shock were identified during the reporting period. There were 5 fatal cases (4 for sepsis).

Therefore, in view of available data regarding sepsis, the PRAC considered that changes to the Product Information were warranted.

The CHMP agrees with the scientific conclusions made by the PRAC.

Grounds recommending the variation to the terms of the Marketing Authorisation

On the basis of the scientific conclusions for Zytiga, the CHMP is of the opinion that the benefit-risk balance of the medicinal product containing the active substance ABIRATERONE is favourable subject to the proposed changes to the product information.

The CHMP recommends that the terms of the Marketing Authorisation should be varied.