22 May 2014
EMA/470711/2014
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/0019

Period covered by the PSUR: 28.04.13 - 27.10.13

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

Scientific conclusions

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

Following a review of the cases of myocardial infarction identified in the post-marketing experience, the fact that ischemic heart disease is an important identified risk in the Risk Management Plan of Zytiga and angina pectoris is an adverse reaction in the Summary of Products Characteristics (SmPC), as well as the biological plausibility and the clinical spectrum of ischemic heart disease, the PRAC considers that changes to the product information are warranted to include myocardial infarction in section 4.8 of the SmPC and relevant section of the Package Leaflet.

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(s) should be varied.