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Committee for Medicinal Products for Human Use (CHMP)

Victrelis

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

International non-proprietary name: boceprevir

Procedure No. EMEA/H/C/002332/PSUV/0030

Period covered by the PSUR: 13 November 2013 – 12 May 2014

Medicinal product no longer authorised

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Scientific conclusions

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

Further to a PRAC request, the MAH provided a signal evaluation on renal impairment based on the data derived from clinical trials, literature and post-marketing case reports. Overall, these elements suggest a link between the use of boceprevir and a mild but not negligible risk of renal impairment, characterized mainly by an increase of blood creatinine or decrease in eGFR generally reversible after the end of therapy. An update of section 4.8 of the Victrelis SmPC to include glomerular filtration rate decreased and renal impairment as new adverse drug reactions is therefore recommended as part of this PSUR procedure.

In addition the drug-drug interaction between boceprevir and maraviroc, a CCR5 antagonist, should be included in section 4.5 of the SmPC. Indeed, an increase of maraviroc exposure is expected when co-administered with boceprevir warranting a dose-adjustment of the CCR5 antagonist at 150mg BID.

The package leaflet is updated accordingly.

Therefore, in view of available data, 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 Victrelis, the CHMP is of the opinion that the benefit-risk balance of the medicinal product containing the active substance boceprevir is favourable subject to the proposed changes to the product information.

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

Medicinal product no longer authorised