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EMA/CHMP/99097/2014
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/0024

Period covered by the PSUR: 13 November 2012 - 12 May 2013

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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:

During the PSUR period, the MAH performed a signal analysis on the risk of pancytopenia and agranulocytosis associated with the use of boceprevir. The analysis showed that the addition of boceprevir to bitherapy with pegIFN/RBV can increase by 2-3 fold the risk of experiencing these blood disorders. The MAH's proposal to include these issues in the Victrelis product information is therefore supported.

Furthermore, the reporting of a single case of priapism in a patient treated with boceprevir and alpha-adrenoreceptor antagonists triggered a signal of a potential drug drug interaction between those drugs through the CYP3A4 pathway. However, the case is not fully convincing as other aetiologies cannot be ruled out. At this stage only a contra-indication between boceprevir and alfuzosin and boceprevir and silodosin can be agreed upon. The recommendations with regard to the other alpha-adrenoreceptor antagonists tamsulosin and doxazosin should be further discussed in the next PSUR.

One convincing case of Stevens Johnson syndrome confirmed by a skin biopsy was reported in a boceprevir-treated subject during this PSUR period. In view of this case, the MAH is recommended to add this serious cutaneous reaction to the product information.

The recommended amendments to the Victrelis SmPC (Section 4.3, section 4.4, section 4.5 and section 4.8) and the package leaflet are specified in Annex I of the PRAC PSUR assessment report.

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.