EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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EMA/CHMP/329265/2014
Committee for Medicinal Products for Human Use (CHMP)

INCIVO

International non-proprietary name: telaprevir

Procedure No. EMEA/H/C/002313/PSUV/0024

Period covered by the PSUR: 20.03.2013 – 19.09.2013

Scientific conclusions and grounds recommending the variation to the terms of the Marketing Authorisation

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Scientific conclusions

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

This is the 4th PSUR for telaprevir covering the reporting period 20 March 2013 to 19 September 2013.

A high number of cases of anaemia were reported in INCIVO-treated patients during the period covered by the PSUR: among the 5377 medically confirmed cases (initial and follow-up) reported during the PSUR, a total of 1893 cases described anaemia events which represents more than one third of the reported cases (35%).

A similar rate was reported in the previous PSUR (32%). As such the haematological risk associated with tritherapy still remains a real concern for physicians. At this stage, the increased risk of anaemia when telaprevir is added to pegIFN/RBV regimen (increase in terms of incidence and severity) and the need of regular blood monitoring are already addressed in the summary of product characteristics of Incivo.

However, the recommendations for the management of this very frequent and potentially severe, even life-threatening side-effect are currently confined to a cross reference to the summary of product characteristics of ribavirin for its reduction guidelines. Therefore PRAC recommends that, as it has been done for boceprevir, a wording stating that ribavirin dose reduction is the preferred strategy for the management of tritherapy-induced anaemia is added in section 4.4 of the SmPC of INCIVO.

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 INCIVO, the CHMP is of the opinion that the benefit-risk balance of the medicinal product containing the active substance TELAPREVIR is favourable subject to the proposed changes to the product information.

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