EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Committee for Medicinal Products for Human Use (CHMP)

INCIVO

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

International non-proprietary name: telaprevir

Procedure No. EMEA/H/C/002313/PSUV/0028

Period covered by the PSUR: 20 September 2013 – 19 March 2014

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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:

Based on a review of pancreatitis, four case reports have been retrieved in literature including two cited in this PSUR. In all these cases, the role of telaprevir is likely or possible. Moreover, when regarding the data derived from clinical trials, those argue in favour of a causal relationship of telaprevir since no cases were reported in the placebo arm versus 35 SAEs with telaprevir therapy. Based on these data, the incidence of pancreatitis can be estimated to be 0.3%.

There have been a total of 138 cumulative reports of pancreatitis with sufficient information for analysis, and there have been approximately 32 cases without additional alternative or confounding factors other than peginterferon and ribavirin.

Therefore, in view of available data regarding pancreatitis, the PRAC considered that changes to the product information were warranted.

In addition, the SmPC has been updated in order to reflect an interaction with maraviroc based on pharmacokinetic data assessed in the variation procedure for Celsentri (EMEA/H/C/000811/II/0035).

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.