EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

24 October 2013
EMA/88224/2014
Committee for Medicinal Products for Human Use (CHMP)

INTELENCE

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

International non-proprietary name: etravirine

Procedure No. EMEA/H/C/000900/PSUV/0033

Period covered by the PSUR: 28 September 2012 to 27 March 2013

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8416
E-mail info@ema.europa.eu **Website** www.ema.europa.eu
An agency of the European Union

Scientific conclusions

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

In line with published data, etravirine AUC, C_{max} and C_{min} were found to decrease by 23%, 24% and 29%, respectively, when co-administered with boceprevir. Boceprevir AUC and C_{max} increased by 10% and C_{min} decreased by 12% in this combination. Co-infections with hepatitis C virus and HIV are frequent. The clinical significance of reductions in etravirine pharmacokinetic parameters and boceprevir C_{min}, especially in the setting of the combination therapy with HIV antiretroviral medicines, which also affect the pharmacokinetics of etravirine and/or boceprevir, is unknown. This warrants introduction of a corresponding warning in the SmPC of etravirine, in line with the already existing warning in the SmPC of boceprevir.

The CHMP agrees with the scientific conclusions made by the PRAC.

In addition, minor editorial changes are made in the recommended wording on interactions with boceprevir, in order to improve consistency with other parts of the Product Information of Intelence.

Grounds recommending the variation to the terms of the Marketing Authorisation

On the basis of the scientific conclusions for Intelence, the CHMP is of the opinion that the benefit-risk balance of the medicinal product containing the active substance etravirine 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.