EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Committee for Medicinal Products for Human Use (CHMP)

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

International non-proprietary name: bosutinib

Procedure No. EMEA/H/C/PSUSA/00010073/201503

Period covered by the PSUR: 04 September 2014 – 03 March 2015

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## Scientific conclusions

Taking into account the PRAC assessment report on the PSUR for bosutinib, the scientific conclusions of CHMP are as follows:

A review of the cardiovascular events received during this reporting interval found five cases of increased blood pressure (including three serious cases) and one cerebrovascular accident (serious). Although these cases were inconclusive for an association between bosutinib exposure and hypertension, increased reporting rates of the events of hypertension was shown in clinical trials in comparison to imatinib, with hypertension being one of the most commonly reported cardiovascular adverse events. In clinical trials, hypertension was reported in about 7.7% patients (cut-off date of 2014) in 1$^{st}$, 2$^{nd}$ and later lines of bosutinib therapy, including 1.2% events considered drug-related. In view of the above, it is considered that hypertension should be reflected as common adverse reaction in the product information for Bosulif.

Therefore, in view of available data regarding Bosulif, 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 bosutinib the CHMP is of the opinion that the benefit-risk balance of the medicinal product containing bosutinib is favourable subject to the proposed changes to the product information

The CHMP recommends that the terms of the marketing authorisation should be varied.