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EMA/CHMP/750482/2014
Committee for Medicinal Products for Human Use (CHMP)

Tafinlar

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

International non-proprietary name: DABRAFENIB

Procedure No. EMEA/H/C/002604/PSUV/0005

Period covered by the PSUR: 26 August 2013 – 26 February 2014

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Scientific conclusions

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

After the data lock of this report, a report of pancreatic adenocarcinoma was received. The report described a 57-year old male who was enrolled in an open-label rollover study (BRF114144). Approximately 946 days after the patient received began treatment with dabrafenib 150 mg twice daily, he was diagnosed with grade 4, biopsy-confirmed KRAS positive adenocarcinoma of the pancreas. Treatment with dabrafenib was discontinued 12 days later. The investigator considered that there was a reasonable possibility that the pancreatic adenocarcinoma may have been caused by dabrafenib. This is the first report of a RAS-mutation positive non-cutaneous malignancy associated with dabrafenib monotherapy treatment. Non cutaneous malignancy is included in the RMP as an identified risk. Pancreatic carcinoma is described in section 4.4 in the context of combination therapy. The information in section 4.4 should be revised to also include monotherapy.

Therefore, in view of available data regarding dabrafenib, 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 Tafinlar, the CHMP is of the opinion that the benefit-risk balance of the medicinal product containing the active substance dabrafenib is favourable subject to the proposed changes to the product information.

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