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Committee for Medicinal Products for Human Use (CHMP)

Scientific conclusions and grounds for the variation to the terms of the marketing authorisation(s)

Active substance(s): trabectedin

Procedure No. EMEA/H/C/PSUSA/00003001/201509

Period covered by the PSUR: 18 September 2014 to 17 September 2015

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Scientific conclusions

Taking into account the PRAC Assessment Report on the PSUR(s) for trabectedin, the scientific conclusions of CHMP are as follows:

During this PSUR reporting period safety data on cardiac toxicity has become available. Cardiac toxicity is a potential short or long-term complication that might be associated with the use of anticancer therapy both conventional chemotherapy but also novel therapies. Following completion of the comparative trial ET743SAR3007, cardiac dysfunction was observed in 20 (5.3%) of 378 patients receiving trabectedin as compared with 4 (2.3%) of 172 patients treated with dacarbazine.

Therefore, in view of the data presented in the reviewed PSUR the PRAC considered that changes to the product information of medicinal products containing trabectadin were warranted.

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

Grounds for the variation to the terms of the marketing authorisation(s)

On the basis of the scientific conclusions for trabectedin the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing trabectedin is unchanged subject to the proposed changes to the product information.

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