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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): niraparib

Procedure No. EMEA/H/C/PSUSA/00010655/201809

Period covered by the PSUR: 25/03/2018 To: 25/09/2018

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Scientific conclusions

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

Following a signal regarding sepsis with niraparib, a number of relevant cases were identified. Overall, in almost half of the presented cases, the causality could not be excluded or was related to the study drug. Niraparib can cause haematological toxicity that includes febrile neutropenia. A possible cause for sepsis is a low neutrophil count and there is a potential association between niraparib and developing sepsis. Overall, the PRAC considered that the preferred term febrile neutropenia was adequate to describe the cases reviewed within this PSUSA. Febrile neutropenia was reported in 2 out of 367 patients in the NOVA trial leading to the frequency uncommon. Therefore, the PRAC concluded that “febrile neutropenia” should be added as a new adverse drug reaction in section 4.8 of the SmPC with the frequency “uncommon.” The package leaflet should be updated accordingly.

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 niraparib, the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing niraparib 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