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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): nivolumab

Procedure No. EMEA/H/C/PSUSA/00010379/201901

Period covered by the PSUR: 4 July 2018 to 3 January 2019

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Scientific conclusions

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

After mono- or combination therapy with nivolumab, CMV infection/reactivation was found in cases where corticosteroid treatment was performed due to immune related colitis. Treatment-resistant colitis following nivolumab exposure should suggest CMV infection, whether the immunodeficiency is due to the malignant tumour disease, exposure to checkpoint inhibitors, treatment with corticosteroids or a combination of these conditions. Infectious and other aetiologies of diarrhoea should be ruled out, therefore appropriate laboratory tests and additional examinations must be performed. If diagnosis of corticosteroid-refractory immune-related colitis is confirmed, addition of an alternative immunosuppressive agent to the corticosteroid therapy, or replacement of the corticosteroid therapy, should be considered. These differential diagnostic considerations are safety relevant and should be added to section 4.4 of the SmPC.

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