30 January 2025
EMA/139530/2025
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): tislelizumab

Procedure No. EMEA/H/C/PSUSA/00000136/202406

Period covered by the PSUR:
25/12/2023 To: 25/06/2024

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Scientific conclusions

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

In view of available data on hemophagocytic lymphohistiocytosis from clinical trials, the literature, spontaneous reports including in two cases a close temporal relationship, a positive de-challenge and in view of a plausible mechanism of action, the PRAC considers a causal relationship between tislelizumab and hemophagocytic lymphohistiocytosis is at least a reasonable possibility. The PRAC concluded that the product information of products containing tislelizumab should be amended accordingly.

In view of available data on cystitis noninfective from clinical trials and the literature including in three cases a close temporal relationship, a positive de-challenge and in view of a plausible mechanism of action, the PRAC considers a causal relationship between tislelizumab and cystitis noninfective is at least a reasonable possibility. The PRAC concluded that the product information of products containing tislelizumab should be amended accordingly.

Having reviewed the PRAC recommendation, the CHMP agrees with the PRAC overall conclusions and grounds for recommendation.

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

On the basis of the scientific conclusions for tislelizumab the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing tislelizumab 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.