16 December 2021
EMA/31563/2022
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): atezolizumab

Procedure No. EMEA/H/C/PSUSA/00010644/202105

Period covered by the PSUR: 18/05/2020 To: 17/05/2021

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Scientific conclusions

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

In view of the presented data on immune-related myocarditis from the company's safety database, which retrieved 605 cases, with the exclusion of 18 cases due to onset prior to treatment initiation, 1 case that had infectious aetiology and 13 that were reported with myositis or rhabdomyolysis, a total of 66 cases had high diagnostic score, including 2 fatal cases with confirmed autoimmune myocarditis, and 27 had corrective treatment with corticosteroids. After reviewing the available data, the PRAC concluded that the product information should be amended in order to include a recommendation to permanently discontinue atezolizumab for ≥ Grade 2 myocarditis.

Additionally, although the risk of diabetes mellitus and diabetic ketoacidosis (DKA) is already included in the SmPC for atezolizumab, the PRAC concluded that the package leaflet (PL) should be amended to include specific signs of DKA, to ensure that patients are fully informed of the risk of DKA and of the particular signs to be aware of.

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 atezolizumab the CHMP is of the opinion that the benefit-risk balance of the medicinal product containing atezolizumab is unchanged subject to the proposed changes to the product information

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