EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

26 April 2019
EMA/CHMP/357412/2019
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): avelumab

Procedure No. EMEA/H/C/PSUSA/00010635/201809

Period covered by the PSUR: 22 March 2018 to 22 September 2018

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Scientific conclusions

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

A signal of pancreatitis was evaluated identifying 16 serious cases and 1 non-serious case in patients treated with avelumab, all reported from clinical trials. Five of these cases were evaluated as possibly related to avelumab: 1 case pertained to avelumab administered as monotherapy, which is the only approved indication in the EU; the remaining 4 cases pertained to avelumab administered as combination therapies. Three of the cases under combination therapy occurred in combination with axitinib, 2 of which had a fatal outcome. All 5 cases have been acknowledged as subject to confounding factors and problematic to extrapolate the findings from the combination therapies-cases into the mono-therapeutic indication applicable in the EU. Nevertheless, the plausible class effect relating to PD-1 and PD-L1 inhibitors and immune-related pancreatitis is acknowledged. Therefore, the SmPC should be updated to include pancreatitis as a rare immune-related adverse drug reaction of avelumab treatment.

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

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