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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): mifamurtide

Procedure No. EMEA/H/C/PSUSA/00002059/201903

Period covered by the PSUR: 4 March 2016 – 4 March 2019

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## Scientific conclusions

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

Based upon the review of the cases, a causal association between mifamurtide and the occurrence of pericardial effusion is considered likely in view of cases with a plausible time-to-occurrence (TTO), absence of other causative factors, and positive dechallenge. In the SmPC of mifamurtide, pericarditis is mentioned in section 4.4. In addition, pericardial effusion is a listed adverse drug reaction (ADR) for another immunostimulant, i.e. aldesleukin. Therefore, the SmPC of mifamurtide should be updated with the inclusion of pericardial effusion as an ADR in section 4.8 under SOC Cardiac disorders. A frequency of 'not known (cannot be estimated from available data)' is considered appropriate. The PL 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 mifamurtide the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing mifamurtide 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.