25 July 2019
EMA/449645/2019
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): lutetium (177Lu) chloride

Procedure No. EMEA/H/C/PSUSA/00010391/201812

Period covered by the PSUR: 19 June 2018 to 19 December 2018

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Scientific conclusions

Taking into account the PRAC Assessment Report on the PSUR(s) for lutetium (177Lu) chloride, the scientific conclusions of the CHMP are as follows:

Five cases of tumour lysis syndrome (TLS) were identified in the scientific literature in association with Lu-177 based radioligand therapy (RLT). The cases occurred in close temporal proximity to the RLT, alternative aetiologies were excluded and most cases either met or were close to meeting formal criteria of TLS definition. All cases recovered with treatment.

The lower bound of the 95 % confidence interval of the reporting odds ratio for tumour lysis syndrome in EudraVigilance in association with Lu-177 is increased at 34.50, with 3 cases. These are duplicates of those identified in the literature.

The PRAC is of the view that although the number of identified cases is limited, the exposure to date is relatively low, and the association with tumour lysis syndrome is biologically plausible. The PRAC therefore recommends that the Product Information 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 lutetium (177Lu) chloride the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing lutetium (177Lu) chloride 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.