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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): lutetium (177Lu) chloride

Procedure No. EMEA/H/C/PSUSA/00010391/201706

Period covered by the PSUR: 20 December 2016 – 19 June 2017

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Scientific conclusions

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

The interim results of the randomised controlled clinical trial NETTER-1 demonstrated evidence of a higher incidence of any grade of alopecia in patients receiving Lu177 peptide receptor radionuclide therapy. In addition to this clinical trial, a number of prospective single-arm studies reported hair loss occurring in more than 50% of patients with neuroendocrine tumours receiving Lu177.

Although the identified studies have limitations, the PRAC noted the consistency with which hair loss has been reported. Moreover, an association with hair loss is biologically plausible. Hair loss can greatly impact quality of life hence the PRAC is of the view that information that it may occur but appears to be generally mild and temporary is valuable to patients. A product information update is therefore recommended.

The CHMP agrees with the scientific conclusions made by the PRAC.

Grounds for the variation to the terms of the marketing authorisations

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 products containing lutetium (177Lu) chloride is unchanged subject to the proposed changes to the product information.

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