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EMA/CHMP/99889/2020
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) oxodotreotide

Procedure No. EMEA/H/C/PSUSA/00010643/201906

Period covered by the PSUR: 19 December 2018 to 19 June 2019

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Scientific conclusions

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

Based on a cumulative review of all Tumour Lysis Syndrome cases, the MAH identified one case describing a patient with a medical history of midgut carcinoid tumour with peritoneal and mesenteric metastases, dehydration due to sub ileus and poor oral intake for months. The patient received Lutathera on an unspecified date and unknown dose. After 10 days of Lutathera administration, the patient was hospitalised for acute kidney injury. The acute kidney injury in the setting indicated above was reported to be due to tumour lysis syndrome. Treatment included five doses of rasburicase (as reported) and was reported as complete recovery. The PRAC considers that a warning should be added to 4.4 of the SmPC regarding tumour lysis Syndrome in line with the SmPC of other medicines with ^{177}Lu radioligand. The Package Leaflet 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) oxodotreotide the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing lutetium (177Lu) oxodotreotide 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.