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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): denosumab (indicated for skeletal related events associated with bone metastases and for giant cell tumour of bone)

Procedure No. EMEA/H/C/PSUSA/00009119/201709

Period covered by the PSUR: 27 September 2016 - 26 September 2017

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Scientific conclusions

Taking into account the PRAC Assessment Report on the PSUR(s) for denosumab (indicated for skeletal related events associated with bone metastases and for giant cell tumour of bone), the scientific conclusions of the CHMP are as follows:

Based on the results from four phase III active-controlled clinical trials in patients with advanced malignancies involving bone, the PRAC considered an update of section 4.8 of the SmPC of XGEVA necessary, in order to reflect that the incidence of new primary malignancy was 54/3691 (1.5%) in the XGEVA treated patients and 33/3688 (0.9%) in the comparator zoledronic acid group and that the difference was statistically significant. The cumulative incidence at one year was 1.1 % for denosumab and 0.6 % for zoledronic acid, respectively. The package leaflet is being updated accordingly. In addition, the PRAC considered a DHPC necessary to inform health care professionals about this new information.

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 denosumab (indicated for skeletal related events associated with bone metastases and for giant cell tumour of bone) the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing denosumab (indicated for skeletal related events associated with bone metastases and for giant cell tumour of bone) 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.