

## **Risk of New Primary Malignancy with Xgeva (denosumab)**

### **Direct Healthcare Professional Communication**

Date: 7th May 2018

Dear Healthcare Professional,

Amgen, in agreement with the European Medicines Agency (EMA) and Malta Medicines Authority would like to inform you of the following:

#### ***Summary***

- **New primary malignancies were reported more frequently in clinical studies in patients with advanced malignancies treated with Xgeva (denosumab) compared to zoledronic acid.**
- **The cumulative incidence of new primary malignancies at one year was 1.1% for denosumab treated patients compared to 0.6% for zoledronic acid treated patients.**
- **No treatment-related pattern in individual cancers or cancer groupings was apparent.**

#### ***Background on the safety concern***

Xgeva (denosumab) is indicated for:

- Prevention of skeletal related events (pathological fracture, radiation to bone, spinal cord compression or surgery to bone) in adults with advanced malignancies involving bone.
- Treatment of adults and skeletally mature adolescents with giant cell tumour of bone that is unresectable or where surgical resection is likely to result in severe morbidity

In a pooled analysis from four phase III studies in patients with advanced malignancies involving bone, new primary malignancy was reported more frequently in patients treated with Xgeva (denosumab 120 mg once monthly) compared to zoledronic acid (4 mg once monthly) during the primary double blind treatment phases of these studies. New primary malignancy occurred in 54/3691 (1.5%) of patients treated with XGEVA (median exposure of 13.8 months; range: 1.0–51.7) and in 33/3688 (0.9%) of patients treated with zoledronic acid

(median exposure of 12.9 months; range: 1.0-50.8). The cumulative incidence at one year was 1.1% for denosumab and 0.6% for zoledronic acid, respectively. No treatment-related pattern in individual cancers or cancer groupings was apparent.

The product information for Xgeva will be updated to include this information.

### ***Call for Reporting***

Please report any adverse reactions to the Medicines Authority by post or e-mail: ADR reporting/ Sir Temi Zammit Building, Malta Life Sciences Park, San Gwann or on [www.medicinesauthority.gov.mt/adrportal](http://www.medicinesauthority.gov.mt/adrportal)

As Xgeva is a biological product, the product name and batch details should also be reported.

▼ Xgeva is subject to additional monitoring. This will allow quick identification of new safety information.

### ***Company contact point***

Should you have any questions or require additional information regarding the use of Xgeva, please contact Medical Information on Cherubino Ltd, Delf Building, Sliema Road, Gzira, GZR 1637. Telephone number 21 343270 and email: [pharmacovigilance@cherubino.com.mt](mailto:pharmacovigilance@cherubino.com.mt) for access to further information

Yours sincerely,



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