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Direct Health Care Professional Communication

Date: October 2017

Title: XGEVA® (denosumab) – Risk of Multiple Vertebral Fractures (MVF) following treatment discontinuation]

Dear Health Care Professional,

Amgen would like to inform you with important new safety information regarding the risk of Multiple Vertebral Fractures (MVF), not due to bone metastases, that may occur following discontinuation of treatment with XGEVA, particularly in patients with risk factors such as osteoporosis or prior fractures.

XGEVA is indicated for:

- the prevention of skeletal related events (pathological fracture, radiation to bone, spinal cord compression or surgery to bone) in adults with bone metastases from solid tumours.
- the 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.

Summary of the safety issue

- Cases of MVF have occurred rarely following discontinuation of XGEVA in patients participating in ongoing clinical trials. These fractures were not due to bone metastases.
- The fractures occurred in post-menopausal women with malignancies who had previous fractures (non-vertebral or vertebral) or who had known osteoporosis.

Consistent with the pharmacological properties of XGEVA, effects on bone are known to be reversible and bone turnover increases after XGEVA is discontinued.

Summary of Recommendations for Health Care Professionals

- Advise patients not to interrupt XGEVA therapy without their physician's advice. When XGEVA treatment is discontinued, evaluate the individual patient's risk for vertebral fractures.

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Action being taken by Amgen

Amgen is proposing to European Medicines Agency (EMA) to include Multiple Vertebral Fractures (MVF) in the Warnings and Precautions and Undesirable Effects sections of the XGEVA prescribing information and patient information leaflet. The MVF update is undergoing review by the EMA.

Further Information

For detailed information regarding XGEVA, it is essential that you read the XGEVA prescribing information and patient information leaflet.

The information in this letter has been approved by the Saudi Food and Drug Authority (SFDA).

Contact details for adverse event reporting or to request further information

Any suspected adverse reactions should be reported immediately to local Amgen QPPV or the National Pharmacovigilance and Drug Safety Center

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The National Pharmacovigilance & Drug safety Centre (NPC)

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Online: http://ade.sfda.gov.sa/

Should you have any questions or require additional information regarding the use of XGEVA, please contact Medical Information on +966 112 799329 or by e-mail at: meamedinfo@amgen.com

Sincerely,

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