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On Drugs and Therapeutics

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IN BRIEF

Denosumab for Bone Metastases

The FDA, which recently approved subcutaneous (SC) administration of denosumab (*Prolia* – Amgen) for treatment of postmenopausal osteoporosis,¹ has now approved the same drug with a different brand name (*Xgeva* – Amgen) and dosage for prevention of skeletal-related events (such as pathologic fracture, spinal cord compression or radiation to bone) in patients with bone metastases from solid tumors. Denosumab is a fully human anti-RANK ligand antibody that inhibits the formation, activation and survival of osteoclasts.²

A prospective, randomized, double-blind trial in 1901 patients with bone metastases from castration-resistant prostate cancer found that denosumab 120 mg injected SC every 4 weeks, compared to the bisphosphonate zoledronic acid (*Zometa*) 4 mg IV, delayed the time to a first skeletal event by 3.6 months (20.7 vs. 17.1 months).³ In 1776 patients with bone metastases from solid tumors or multiple myeloma, the mean time to a first skeletal event was 20.6 months with SC denosumab and 16.3 months with IV zoledronic acid.⁴

Denosumab can lower serum calcium concentrations, especially in patients with impaired renal function. Fatigue is the most commonly reported adverse effect. Other adverse effects of both denosumab and zoledronic acid in clinical trials have included nausea, dyspnea and diarrhea. Acute-phase reactions and renal toxicity have been less frequent with denosumab than with zoledronic acid. Osteonecrosis of the jaw, which can occur with bisphosphonates, has also been reported with denosumab.

1. Denosumab (*Prolia*) for postmenopausal osteoporosis. *Med Lett Drugs Ther* 2010; 52: 81.

2. A Lipton and C Goessl. Clinical development of anti-RANKL therapies for treatment and prevention of bone metastasis. *Bone* 2011; 48:96.
3. K Fizazi et al. A randomized phase III trial of denosumab versus zoledronic acid in patients with bone metastases from castration-resistant prostate cancer. *J Clin Oncol* 2010; 28:18s (abstr LBA4507).
4. D Henry et al. A double-blind, randomized study of denosumab versus zoledronic acid for the treatment of bone metastases in patients with advanced cancer (excluding breast and prostate cancer) or multiple myeloma. *Eur J Cancer Suppl* 2009; 7:11 (abstr 20LBA).

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