A Randomized Open-Label Study to Evaluate the Safety and Efficacy of Denosumab and Ibandronate in Postmenopausal Women Sub-Optimally Treated With Daily or Weekly Bisphosphonates

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Abstract

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Purpose: Denosumab, a fully human monoclonal antibody that specifically targets RANKL to inhibit osteoclast formation, function, and survival, reduces risk for vertebral, non-vertebral, and hip fractures.1 In subjects who were treatment naïve or previously treated with alendronate, denosumab was associated with greater gains in bone mineral density (BMD) and decreases in bone turnover markers when compared with alendronate-treated subjects.2,3 The purpose of this open-label trial was to compare the safety and efficacy of denosumab with ibandronate over 12 months in postmenopausal women with low BMD who were sub-optimally treated with prior bisphosphonate therapy.

Methods: This was a multicenter, randomized, open-label, parallel-group study in which postmenopausal women age 55 and older were randomized 1:1 to receive open-label denosumab 60mg subcutaneously every 6 months or ibandronate 150mg orally every month for 12 months. Percent change from baseline in total hip (TH, primary endpoint), femoral neck (FN), and lumbar spine (LS) BMD at month 12, percent change from baseline in serum CTX (sCTX) at 1 and 6 months, and safety were assessed.

Results: Randomized subjects (n=833; 417, denosumab; 416, ibandronate) had a mean (SD) age of 66.7 (8.0) years and mean (SD) BMD T-score of -1.8 (0.7), -2.1 (0.7), and -2.5 (0.8) at the TH, FN, and LS, respectively. Denosumab significantly increased TH BMD compared with ibandronate at 12 months (2.2% vs 0.9%, respectively; p<0.0001). Denosumab also significantly increased BMD at the FN (1.7% vs 0.5%) and LS (4.1% vs 2.1%) compared with ibandronate (p<0.0001 at both sites). Denosumab significantly decreased sCTX at 1 month with a median change from baseline of -81.1% compared to -35.0% for ibandronate (p<0.0001), and sCTX remained decreased through 6 months of treatment. In this open-label study, overall adverse events were similar between groups. Reports classified as serious adverse events (SAEs) were more frequent in subjects treated with denosumab than with ibandronate. No organ system accounted for a preponderance of these reports. The incidence of SAEs involving infection and malignancy was similar between groups.

Conclusions: Denosumab treatment resulted in greater increases in BMD at all measured sites compared with ibandronate. No new safety risks were identified in this open-label study.


Disclosures:
Christopher Recknor: Roche, GSK, Eli-Lilly, Procter & Gamble, Merck, Novartis, Amgen, NPS, Zelos, Eli-Lilly, Roche, Procter & Gamble, GSK, Merck, sonofi-aventis #5

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