BACKGROUND: Denosumab (DMAB) is an approved therapy for the treatment of postmenopausal women with osteoporosis at increased risk for fracture. The effects of DMAB treatment for up to 10 years are being evaluated in the 3-year FREEDOM study and its 7-year extension.

OBJECTIVES: To report the 5-year results of the FREEDOM extension study, representing up to 8 years of DMAB treatment.

METHODS: During the extension, all women received 60 mg of DMAB every 6 months and daily calcium and vitamin D. In this analysis, women in the long-term group received 8 years of DMAB (3 years in FREEDOM and 5 years in the extension); women in the cross-over group received 5 years of DMAB (3 years of placebo in FREEDOM and 5 years of DMAB in the extension).

RESULTS: Of the women who entered the extension, 66% completed the 5th year. With 8 years of DMAB treatment in the long-term group, mean bone mineral density (BMD) continued to increase from FREEDOM baseline for cumulative gains of 18.4% at the lumbar spine (LS) and 8.3% at the total hip (TH) (all p<0.0001). With 5 years of DMAB treatment in the cross-over group, there were mean BMD increases from extension baseline of 13.1% at the LS and 6.2% at the TH (all p<0.0001). Serum C-telopeptide was rapidly and similarly reduced after each DMAB dose, with the characteristic attenuation of effect at the end of the dosing period. Incidence of new vertebral and nonvertebral fracture continued to remain low throughout the extension; during year 8, hip fracture incidence was 0.2% and 0.1% for the long-term and cross-over groups, respectively. Overall incidences of adverse events (AEs) and serious AEs were consistent with data reported previously in the extension study.

CONCLUSIONS: DMAB treatment for up to 8 years was associated with continued increases in BMD, persistent reduction of bone turnover, and low fracture incidence. The benefit/risk profile for DMAB remains favorable.

Disclosure of Interest:

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