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DENOSUMAB TREATMENT IN POSTMENOPAUSAL WOMEN WITH OSTEOPOROSIS FOR UP TO 9 YEARS: RESULTS THROUGH YEAR 6 OF THE FREEDOM EXTENSION

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Objective: To report the results through year 6 of the FREEDOM open-label Extension (Ext), representing up to 9 years of continued denosumab (DMAb) for the treatment of postmenopausal osteoporosis.

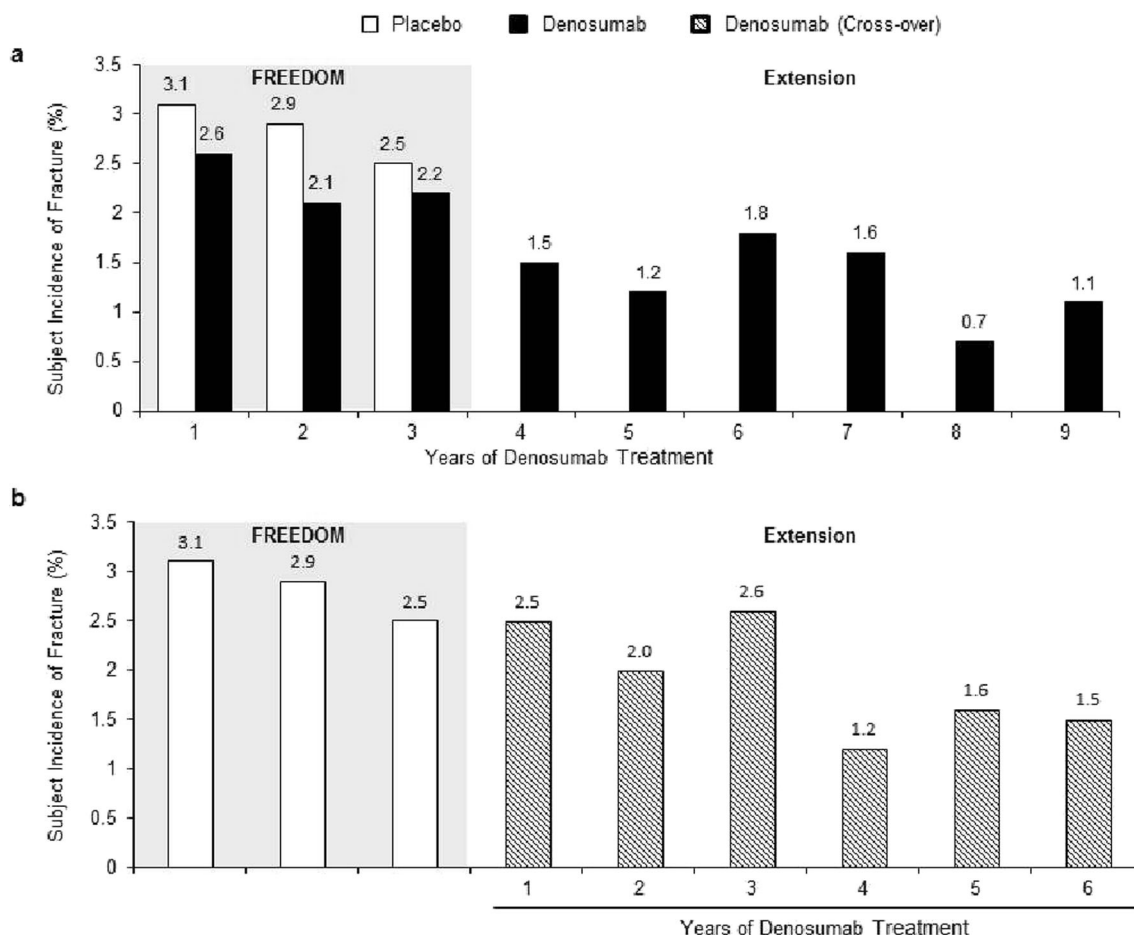
Material and Methods: During the Ext, all women received 60 mg DMAb every 6 months, and daily calcium and vitamin D. At Ext year 6, bone turnover markers, nonvertebral fracture

incidence, and adverse events were evaluated. In these analyses, women in the long-term group received up to 9 years of DMAb (3 years in FREEDOM and up to 6 years in the Ext); women in the cross-over group received up to 6 years of DMAb (3 years of placebo in FREEDOM and up to 6 years of DMAb in the Ext), allowing replication of results from the long-term group.

Results: Of the women who enrolled in the Ext, 3,098 (68 %) were still on study at the beginning of year 6, with a mean age of 79 years (range 68–98 years). In both groups, serum CTx and PINP were similarly reduced after each DMAb dose. The characteristic attenuation was observed through each dosing period and reductions were sustained through Ext year 6. The yearly incidences of nonvertebral (Figure) and major nonvertebral fractures remained low in both groups. Rates of adverse events and serious adverse events were consistent with previously reported Ext data. In Ext year 6, 2 events were adjudicated positive for ONJ in the cross-over group; there were no cases of atypical femoral fracture in either group.

Conclusion: In this aging population, DMAb treatment for up to 9 years maintained reduced bone turnover and was associated with continued low incidence of nonvertebral and major nonvertebral fractures. The benefit/risk profile remained favorable.

Disclosures: S Papapoulos: Consultant/Advisory activities - Amgen Inc., Axsome, Gador, GSK, Merck, Novartis, UCB; Board membership - IOF. C Roux: Grant/Research support - Bongrain, Lilly, MSD; Consultant/Advisory activities - Amgen Inc., MSD; Board membership - Amgen Inc., MSD, UCB. HG Bone - Grant/Research support - Amgen Inc., Merck, Novartis; Consultant/Advisory activities - Amgen Inc., Merck, Mission, Novartis. P Dakin, NS Daizadeh, A Wang, M Gavin, and RB Wagman: Company employee - Amgen Inc.; Stock/Stock options - Amgen Inc. E Czerwiński: Grant/Research support - Amgen Inc. D Frey: Grant/Research support - Abbott, Amgen Inc., Daiichi-Sankyo, Novartis, UCB; Consultant/Advisory activities - Amgen Inc., Meda, Takeda. D Kendler: Grant/Research support - Amgen Inc., Astalis, Astra Zeneca, Eli Lilly, GSK,

Figure. Yearly Incidence of Nonvertebral Fractures in the (a) Long-term and (b) Cross-over Groups Through Extension Year 6

Novartis; Consultant/Advisory activities - Amgen Inc., Eli Lilly, GSK, Merck, Pfizer; Speaker's bureau - Amgen Inc., Eli Lilly, Novartis. EM Lewiecki: Grant/Research support - Amgen Inc., Lilly, Merck; Consultant/Advisory activities - AgNovos, Alexion, Amgen Inc., Lilly, Merck, NPS, Radius Health; Board membership - National Osteoporosis Foundation, ISCD. J Malouf and D Mellström: Nothing to disclose. J-Y Reginster: Grant/Research support - Amgen Inc., Bristol Myers Squibb, GSK, Lilly, Merck Sharp & Dohme, Novartis, Roche, Rottapharm, Servier, Teva. Consultant/Advisory activities - Amgen Inc., GSK, Lilly, Merckle, Negma, Novartis, NPS, Nycomed, Roche, Servier, Theramex, UCB, Wyeth. Lecture fees - Analis, Ebewe Pharma, Genevrier, GSK, IBSA, Lilly, Merck Sharp & Dohme, Nolver, Novartis, Novo-Nordisk, Nycomed, Roche, Rottapharm, Servier, Teijin, Teva, Theramex, Zodiac. H Resch: Grant/Research support - Amgen Inc., Lilly; Consultant/Advisory activities - Amgen Inc., Lilly, MSD; Speaker's bureau - Amgen Inc., Lilly, MSD, UCB. ML Brandi: Grant/Research support - Abiogen, Alexion, Amgen Inc., Bruno Farmaceutici, Eli Lilly, MSD, NPS, Servier, Shire, SPA; Consultant/Advisory activities - Abiogen, Alexion, Amgen Inc., MSD, NPS, Servier, Shire, SPA; Board membership: Alexion, Servier.