[2011] [OP0289] LONG-TERM TREATMENT OF POSTMENOPAUSAL OSTEOPOROTIC WOMEN WITH STRONTIUM RANELATE: RESULTS AT 10 YEARS

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Background: Postmenopausal osteoporosis is a chronic disease requiring long-term treatment. Strontium ranelate (SrRan) 2g/day has proven efficacy against vertebral and non vertebral fractures including hip over 5 years in postmenopausal women. Results showing the continuous benefit on osteoporotic fractures and bone mineral density (BMD) over 8 years have already been reported (1).
Objectives: This abstract presents efficacy results over 10 years.
Methods: The two double blind placebo-controlled phase III studies included a total of 6740 Caucasian women with postmenopausal osteoporosis. In SOTI, patients were randomly assigned to receive SrRan 2g/day or placebo for 4 years and during the 5th year, half of the SrRan group continued with SrRan. In TROPOS, patients were randomly assigned to receive SrRan 2g/day or placebo for 5 years. Patients having participated in both studies up to 5 years were invited to enter a 3-year open-label extension study, subsequently extended by 2 years, and then received strontium ranelate up to 10 years. Here are presented the efficacy results in patients treated with SrRan for 10 years.
Results: At SOTI and TROPOS baseline, patients treated for 10 years (n=233) had a profile similar to the whole population with a mean (SD) age of 72.0 (5.5) years, a mean (SD) lumbar spine and femoral neck BMD T-score of –3.30 (1.38) and –2.95 (0.57) respectively. Over the 10-year period, lumbar BMD increased continuously and significantly ($p<0.05$ up to year 10) with, at 10 years, a relative change from baseline of 34.5%±20.2. At the femoral neck and total hip sites, the BMD increased significantly until year 7, with a relative change from baseline of 10.7%±12.1 and 11.7%±13.6 respectively, and then remained stable.
The cumulative incidences of new vertebral and non vertebral fractures (20.6% and 13.7% respectively) over the 5-year extension were not statistically different ($p=1.00$ and 0.672 respectively) to the cumulative incidences over the 5 years in the original studies (18.5% and 12.9% respectively). To assess the anti-fracture efficacy of SrRan in the absence of placebo group, we searched for a matching population in the placebo group of TROPOS using the 10-year probability of major osteoporotic fracture calculated with FRAX® as matching variable. The mean 10-year probability of major osteoporotic fracture, calculated with FRAX®, in the 233 patients treated for 10 years with SrRan was 25.8% at the time of their inclusion in the extension study. The incidences of vertebral and non-vertebral fracture observed over the 5 years of TROPOS were significantly higher ($p<0.05$) in the matching placebo group than those observed in the "10-year" population over the 5- year extension, with a relative risk reduction with SrRan of 35% and 38% for vertebral fractures and non-vertebral fractures respectively.
Strontium ranelate remained safe and well tolerated over 10 years with no unexpected adverse event.
Conclusions: These results are in favour of the maintenance of the efficacy of strontium ranelate over 10 years, with a good safety profile.
References:

1. Reginster JY et al. Long-term treatment of postmenopausal osteoporosis with strontium ranelate: results at 8 years Bone 2009;45(6):1059-1064

Disclosure of Interest: J.-Y. Reginster Grant/Research support from: Bristol Myers Squibb, Merck Sharp&Dohme, Rottapharm, Teva, Lilly, Novartis, Roche, GlaxoSmithKline, Amgen, Servier, Consultant for: Servier, Novartis, Negma, Lilly, Wyeth, Amgen, GlaxoSmithKline, Roche, Merckle, Nycomed, NPS, Theramex, UCB, Speakers Bureau: Merck Sharp&Dohme, Lilly, Rottapharm, IBSA, Genevrier, Novartis, Servier, Roche, GlaxoSmithKline, Teijin, Teva, Ebewee Pharm, Zodiac, Analis, Theramex, Nycomed, Novo-Nordisk, J.-M. Kaufman Grant/Research support from: Amgen, Daiichi-Sankyo, GlaxoSmithKline, Merck Sharp&Dohme, Novartis, Nycomed, Servier and Roche, Consultant for: Amgen, Daiichi-Sankyo, GlaxoSmithKline, Merck Sharp&Dohme, Novartis, Nycomed, Servier and Roche, Speakers Bureau: Amgen, Daiichi-Sankyo, GlaxoSmithKline, Merck Sharp&Dohme, Novartis, Nycomed, Servier and Roche, J.-P. Devogelaer Grant/Research support from: participation in most of trials with antiosteoporotic drugs, C.-L. Benhamou: None Declared, C. Roux Grant/Research support from: Servier, Merck Sharp&Dohme, Amgen, Novartis, Roche, Lilly, Speakers Bureau: Servier, Merck Sharp&Dohme, Amgen, Novartis, Roche, Lilly

Citation: Ann Rheum Dis 2011;70(Suppl3):167