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P42SU. WEEKLY DOSING OF ORAL IBANDRONATE IS EFFECTIVE IN THE PREVENTION OF POSTMENOPAUSAL OSTEOPOROSIS

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Aim: Oral bisphosphonates (BPs) are becoming increasingly important in the prevention of postmenopausal osteoporosis

Abstracts

(PMO). Weekly dosing of BPs may offer advantages over daily dosing in terms of patient preference, convenience and compliance. Ibandronate is a potent nitrogen-containing BP that can be administered intermittently. Oral ibandronate provides highly significant fracture reduction when administered with a drug-free interval of 9-10 weeks, in PMO. This phase II/III study investigated the efficacy, safety and optimal dose of oral weekly ibandronate in the prevention of PMO.

Methods: In this multicentre, double-blind, placebo-controlled study, 630 postmenopausal women were randomised to one of four strata based on time since menopause (TSM) and baseline lumbar spine (L1-L4) bone mineral density (BMD): stratum A, normal BMD, TSM up to 3 years; stratum B, osteopenic, TSM up to 3 years; stratum C, normal BMD, TSM >3 years; and stratum D, osteopenic, TSM >3 years. Patients received calcium supplementation (500mg daily) plus oral weekly ibandronate 5mg (n = 159), 10mg (n = 154) or 20mg (n = 159) or placebo (n = 158) for 2 years. The primary endpoint was relative change from baseline in lumbar spine BMD (L1-L4).

Results: After 2 years, oral weekly ibandronate produced a dose-related and consistent increase in BMD at the lumbar spine and hip (total hip, femoral neck, trochanter, Ward's triangle), relative to baseline. Consistent results were seen across strata; greatest increases in lumbar spine BMD were seen with 20 mg in osteopenic women with TSM >3 years (stratum D: relative BMD increase from baseline 3.6% vs 2.9% across all strata vs -1.1% with placebo). The 10 mg dose maintained bone mass. BMD increases correlated with dose-dependent and sustained reductions in bone turnover markers. Oral weekly ibandronate was well tolerated and no safety concerns were identified.

Conclusions: Oral weekly ibandronate provides dose-dependent increases in BMD at the lumbar spine and total hip. The most significant and substantial BMD gains are with 20 mg. Weekly oral ibandronate holds promise as an effective, well-tolerated and convenient alternative to oral daily BPs for the prevention of PMO.