EFFECTS OF CONJUGATED ESTROGENS/BAZEDOXIFENE ON BONE AND QUALITY OF LIFE IN A EUROPEAN SUBPOPULATION OF POSTMENOPAUSAL WOMEN: A POOLED ANALYSIS OF RANDOMIZED CONTROLLED TRIALS

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Introduction: Conjugated estrogens/bazedoxifene (CE/BZA), a tissue selective estrogen complex, prevented bone loss and improved health-related quality of life (HRQOL) in the Selective estrogens, Menopause, and Response to Therapy (SMART) trials. The effects of CE/BZA on bone mineral density (BMD), bone turnover markers (BTM), and HRQOL (to assess the impact of menopausal symptoms) were evaluated in a European subpopulation of SMART-1 and -5.

Methods: Data were pooled from 2 randomized, double-blind, placebo (PBO)- and active-controlled 12- to 24-month trials in nonhysterectomized postmenopausal women (some with vasomotor symptoms at baseline) who received CE/BZA or PBO. European women with evaluable BMD (n=60), BTM (n=56), and Menopause-specific QOL (MENQOL) questionnaire (n=236) data were included in a pooled subpopulation analysis.

Results: At month 12, CE 0.45 mg/BZA 20 mg and CE 0.625 mg/BZA 20 mg significantly improved BMD (percent change, adjusted difference vs PBO) in lumbar spine (LS) (2.5%, 2.9%, respectively; both P<0.011) and total hip (TH) (1.7%, 2.2%, respectively, both P<0.002) and serum BTMs (median percent change) in osteocalcin (-31.1%, -33.1%, respectively) and c-telopeptide (-48.5 %, -36.8%, respectively) vs PBO (6.7%, 4.2%; P <0.001 for all). Significantly more patients achieved BMD response (change from baseline >=0%) with CE 0.45 mg/BZA 20 mg and CE 0.625 mg/BZA 20 mg (LS: 42.1% [P=0.07], 70.8% [P<0.001]; TH: 52.6%, 75.0%, both P<0.003) vs PBO (11.8%, 5.9%, respectively). MENQOL vasomotor symptoms at month 12 were significantly improved with CE 0.45 mg/BZA 20 mg and CE 0.625 mg/BZA 20 mg (-2.1, -2.2, both P<0.001) vs PBO (-0.7).

Conclusions: CE/BZA for 12 months effectively prevented bone loss and improved HRQOL related to vasomotor function in European postmenopausal women. Findings are consistent with those from the global subject population.