

**[2004] [FRI0394] ETORICOXIB DEMONSTRATES SIMILAR EFFICACY AND IMPROVED GASTROINTESTINAL SAFETY COMPARED TO NAPROXEN IN TWO 138-WEEK RANDOMIZED STUDIES OF OSTEOARTHRITIS PATIENTS**

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**Background:** Etoricoxib, a selective COX-2 inhibitor, has demonstrated clinical efficacy in the treatment of osteoarthritis (OA). Patients with OA of the hip or knee participated in one of two replicate 52-week Base studies, each of which was followed by an 86-week Extension. **Objectives:** To assess maintenance of efficacy and tolerability of etoricoxib 60mg once daily and naproxen 500mg twice daily over a 138-week treatment period. **Methods:** Each Base study consisted of a 12-week placebo- and active-comparator-controlled period (Part I) followed by a 40-week active-comparator controlled period (Part II); this was subsequently followed by an 86-week active-comparator Extension period. The Extensions were double-blind, parallel-group studies and were conducted in 80 sites in 19 countries. Patients taking placebo in Part I were randomly assigned to take etoricoxib 60mg (50%) or naproxen 1000mg (50%) in Part II and the Extension. Patients taking etoricoxib 60mg or naproxen 1000mg in Part I remained on the same regimen throughout the Base study and Extension. The primary efficacy endpoints were Patient Global Assessment of Disease Status and Pain and Physical Function Subscales of the WOMAC questionnaire. Safety and tolerability were assessed by adverse experience (AE), laboratory and physical evaluations. **Results:** Of the 997 patients who entered the Base study, 615 completed the Base study. Of the 463 patients (246 on etoricoxib 60mg and 217 on naproxen 1000mg) who consented to enter the Extension, 161 (etoricoxib 60mg) and 151 (naproxen 1000mg) patients completed 138 treatment weeks. Similar efficacy was observed for patients taking etoricoxib 60mg or naproxen 1000mg during the 86-Week Extension and treatment effects were maintained over time. Baseline, 52-week, and 138-week mean values of WOMAC Pain subscale (100mm scale) for patients on etoricoxib 60mg and naproxen 1000mg were 67mm and 67mm; 28mm and 29mm; and 34mm and 33mm, respectively. Etoricoxib 60mg was generally well tolerated over a 138-week treatment period. Compared with patients taking etoricoxib 60mg, those on naproxen 1000mg had higher incidences of clinical AEs (72.8% vs 83.4%) and drug-related clinical AEs (17.1% vs 26.7%). The safety and tolerability profile for the entire 138 weeks of treatment were similar to that of the 52-week Base study and no new AEs were revealed. Etoricoxib 60mg continued to have an improved gastrointestinal (GI) safety profile compared with naproxen 1000mg; 0.8% (etoricoxib 60mg) and 5.9% (naproxen 1000mg) of patients had one or more upper GI perforation, ulcer or bleeding AEs, confirmed by independent external adjudication. The renal-vascular profile, including hypertension and edema, was similar between etoricoxib 60mg and naproxen 1000mg. **Conclusion:** Etoricoxib 60mg and naproxen 1000mg demonstrate similar efficacy in the long-term treatment of OA. In patients taking etoricoxib 60mg or naproxen 1000mg, efficacy is maintained for 138 weeks. Etoricoxib 60mg has a more favorable GI safety profile compared to naproxen. Sponsored by Merck & Co., Inc. Whitehouse Station, NJ USA

**Osteoarthritis Clinical aspects and treatment**

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