PSORIASIS

ADALIMUMAB EFFICACY IN NAIL PSORIASIS BY BASELINE SUBGROUPS, AND OVERALL SAFETY FROM FIRST 26 WEEKS OF A PHASE-3, RANDOMIZED, PLACEBO-CONTROLLED TRIAL

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Introduction and Objective: Disease burden for plaque psoriasis and concomitant fingernail psoriasis has been shown to be higher compared to plaque psoriasis alone. We report efficacy of originator adalimumab (ADA) in patients with moderate-to-severe fingernail psoriasis, by baseline subgroups, and overall safety.

Materials and Methods: 217 patients were randomized 1:1 to 40mg ADA every-other-week (initial 80mg dose at week 0), or matching placebo (pbo) for the initial 26-weeks. We report achievement of ≥75% improvement from baseline in total fingernail modified Nail Psoriasis Severity Index (mNAPSI 75) for baseline subgroups. Statistical significance for efficacy was determined for ADA vs pbo. Missing data were handled by Multiple Imputation.

Results: Of 217 randomized patients (108 pbo, 109 ADA), 188 (86.6%) completed 26 weeks. The mNAPSI 75 response rate at week 26 was 3.4% pbo and 46.6% ADA; and by baseline subgroups, respectively, was as follows. Median duration of psoriasis (<15.5; ≥15.5 years): 4.1% (n=60) pbo vs 40.5% (n=48) ADA; 2.5% (n=48) pbo vs 51.4% (n=61) ADA. Median duration of nail psoriasis (<8.7; ≥8.7 years): 4.1% (n=58) pbo vs 46.2% (n=50) ADA; 2.5% (n=50) pbo vs 46.9% (n=59) ADA. History of psoriatic arthritis (yes; no): 0.5% (n=32) pbo vs 61.5% (n=30) ADA; 4.6% (n=76) pbo vs 40.9% (n=79) ADA. Median Psoriasis Area Severity Index score (<10.5; ≥10.5): 3.0% (n=50) pbo vs 43.5% (n=57) ADA; 3.7% (n=58) pbo vs 50.0% (n=52) ADA. All results were statistically significant vs pbo (P<0.001). Treatment-emergent adverse events (AEs) over 26 weeks for pbo (N=108) and ADA (N=109) groups, respectively, were: any AE (56.5% and 58.7%); serious AEs (4.6% and 7.3%); infection (27.8% and 29.4%); serious infection (1.9% and 3.7%). There were no

deaths.

Conclusion: Following 26 weeks of treatment, originator ADA resulted in significant mNAPSI 75 improvements across the reported baseline-characteristic subgroups; no new safety risks were identified.