ATOPIC ECZEMA/DERMATITIS

ACHIEVING AN ITCH-FREE STATE WITH UPADACITINIB: A POST-HOC ANALYSIS OF DATA FROM THE PHASE 2B RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED TRIAL IN MODERATE-TO-SEVERE ATOPIC DERMATITIS

Ji Silverberg [(1)] - K Reich [(2)] - B Calimlim [(3)] - Y Gu [(3)] - X Hu [(3)] - H Teixeira [(3)] - E Guttman-yassky [(4)]

Northwestern University Feinberg School Of Medicine, Dermatology, Chicago, Illinois, United States [(1)] - Dermatologikum Berlin And Sciderm Research Institute, Dermatology, Hamburg, Germany [(2)] - Abbvie Inc., Dermatology, North Chicago, Illinois, United States [(3)] - Icahn School Of Medicine At The Mount Sinai Medical Center, Dermatology, New York, New York, United States [(4)]

Introduction: Atopic dermatitis (AD) is a chronic, inflammatory skin disease characterized by pruritus and eczematous lesions. The selective JAK-1 inhibitor, upadacitinib, is being investigated for the treatment of AD.

Objective: To compare the proportions of upadacitinib-treated patients achieving an itch-free state versus placebo.

Methods: 16-week data from the phase-2b upadacitinib trial of adults with moderate-to-severe AD randomized to once-daily upadacitinib monotherapy 7.5, 15, or 30 mg (n=42/42/42), or placebo (n=41) were analyzed. Patient-reported itch was assessed daily using a Numerical Rating Scale (NRS) (0=no itch; 10=worst imaginable itch). An itch-free state was defined as a pruritus NRS weekly rolling average of 0-1 after rounding to the nearest integer; weeks were tallied to characterize the time spent in an itch-free state. Missing data were addressed using non-responder imputation; group differences were assessed by the Cochran-Mantel-Haenszel test.

Results: At baseline, subjects reported a pruritus NRS weekly rolling average of 6.5. At week 16, the proportion of itch-free subjects was 2.4% for placebo and 21.4%/26.2%/40.5% for upadacitinib 7.5/15/30 mg, with 2.9% and 19.6%/25.4%/47.5% of weeks spent itch-free across the 16-week period, respectively. Differences in the proportion of itch-free subjects versus placebo were observed at Week 3 (7.5 mg: 14.0%, p=.012; 15 mg: 21.3%, p<.001; 30 mg: 52.3%, p<.001), with differences observed as early as Week 1 for upadacitinib 30 mg and Week 2 for upadacitinib 15 mg. Differences versus placebo

were also observed at Week 16 (7.5 mg: 18.6%, p=.005; 15 mg: 23.8%, p<.001; 30 mg: 37.7%, p<.001). Similar results were observed for Scoring AD (SCORAD) itch and Patient Oriented Eczema Measure (POEM) itch.

Conclusions: Upadacitinib treatment for 16 weeks resulted in significant improvements in pruritus versus placebo. Upadacitinib-treated subjects achieved a higher proportion and duration of an itch-free state. The positive benefit/risk profile of upadacitinib supports proceeding to phase-3 trials in AD.