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Minimal-to-no itch with baricitinib in patients with moderate-to-severe atopic dermatitis: results from three randomized, phase 3 clinical trials

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Introduction & Objectives: Patients with atopic dermatitis (AD) report symptoms of itch and sleep disturbance, which can have a significant impact on quality of life. Baricitinib, an oral selective JAK1/JAK2 inhibitor, is approved in many countries for moderate-to-severe AD in adults. Here we assessed minimal-to-no itch over 16-weeks treatment with baricitinib monotherapy or in combination with topical corticosteroids (TCS).

Materials & Methods: Minimal-to-no itch was evaluated in patients with moderate-to-severe AD in two baricitinib monotherapy trials (BREEZE-AD1; NCT03334396 and BREEZE-AD2; NCT03334422) and one baricitinib and TCS combination trial (BREEZE-AD7; NCT03733301). Minimal-to-no-itch (score of 0/1) was assessed at Week-2 and Week-16 using the Itch Numeric Rating Scale (NRS): 11-point scale from 0 (“no itch”) to 10 (“worst itch imaginable”). Data from monotherapy trials were integrated and results for BREEZE-AD1/AD2 and BREEZE-AD7 are shown respectively for baricitinib 4-mg (n=248 and n=111), the recommended dose for most patients, versus placebo (n=493 and n=109). Data after discontinuation or rescue were excluded from the analysis. Logistic regression was used to analyze the data with non-responder imputation. Analyses were not adjusted for multiplicity.

Results: In the monotherapy studies, a higher proportion of patients treated with baricitinib 4-mg achieved an Itch NRS score of 0/1 at Week-2 compared to placebo (8.9% versus 1.6%; $p<0.0001$) and these improvements continued to increase to Week-16 (14.1% versus 3.9%; $p<0.0001$). In the combination study, a higher proportion of patients treated with baricitinib 4-mg achieved an Itch NRS score of 0/1 compared to placebo at Week-2 (16.2% versus 2.8%; $p=0.0064$) and maintained these improvements through to Week-16 (22.5% versus 8.3; $p=0.0287$).

Conclusion: Overall, minimal-to-no itch was observed in patients with moderate-to-severe AD as early as Week-2 and continued through Week-16 of treatment with baricitinib 4-mg. Total or near total itch relief can be achieved with baricitinib monotherapy and combination therapy with TCS compared to placebo.

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