Long-term efficacy of baricitinib 2-mg for the treatment of atopic dermatitis in North America

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Introduction:
Baricitinib, an oral, selective Janus Kinase (JAK)1/JAK2 inhibitor, improved disease in adults with moderate-to-severe atopic dermatitis (AD) in a 16-week placebo-controlled study.¹ We report long-term efficacy of baricitinib 2-mg by integrating a Phase 3 trial (BREEZE-AD5; NCT03435081) and its long-term, open-label extension (BREEZE-AD6; NCT03559270).

Methods:
Adults with moderate-to-severe AD received baricitinib monotherapy in BREEZE-AD5. After Week 16, responders could continue in BREEZE-AD5 while partial and non-responders could transition to baricitinib 2-mg in BREEZE-AD6. Responders from BREEZE-AD5 who later lost response or completed Week 104 were also eligible for BREEZE-AD6. Low-potency topical corticosteroids (TCS) were permitted after Week 16 in BREEZE-AD5 and throughout BREEZE-AD6. Proportions of patients with ≥75% improvement from baseline in Eczema and Severity Index (EASI75), vIGA-AD™ score of 0 or 1 (0, 1), and Dermatology Life Quality Index (DLQI) score ≤5 (among those with baseline score >5), as well as mean SCORing AD (SCORAD) visual analog scales of itch and sleeplessness scores and mean percent change from baseline in EASI score were assessed through 52 weeks of continuous baricitinib 2-mg treatment. Data were censored after TCS rescue during the first 16 weeks. Last observation carried forward was applied to missing data.

Results:
This integrated analysis included 146 baricitinib-2-mg-treated patients. Mean baseline EASI score was 26.6. At Weeks 16, 32, and 52, respectively, mean percent change from baseline in EASI score was -50.1%, -59.1%, and -56.8%, and EASI75 responses were observed in 39.6%, 51.4%, and 48.6% of patients. Proportions of patients with vIGA-AD (0, 1) were 27.1%, 38.2%, and 31.3% at Weeks 16, 32, and 52, respectively. Mean SCORAD pruritus score improved from 7.7 at baseline to 4.8 at Week 16 and was maintained at Weeks 32 (3.8) and 52 (4.3). Mean SCORAD sleeplessness score improved from 6.5 at baseline to 3.9 at Week 16 and remained stable through Weeks 32 (3.4) and 52 (3.7). In 129 patients with baseline DLQI >5, 38.6%, 48.8%, and 44.9% had DLQI scores ≤5 at Weeks 16, 32, and 52, respectively, indicating a small or no effect of AD on quality of life.

Conclusion:
Baricitinib 2-mg demonstrated long-term efficacy in adults with moderate-to-severe AD. With long-term therapy (up to 52 weeks), patients treated with baricitinib 2-mg continued to maintain disease control as assessed by decreased skin inflammation and itch and improved sleep and quality of life.
References