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ATOPIC ECZEMA/DERMATITIS

EFFICACY AND SAFETY OF BARICITINIB IN MODERATE TO SEVERE ATOPIC DERMATITIS: RESULTS OF TWO PHASE 3 MONOTHERAPY RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED 16-WEEK TRIALS (BREEZE-AD1 AND BREEZE-AD2)

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Introduction: BREEZE-AD1 (NCT03334396) and BREEZE-AD2 (NCT03334422) are the first of seven phase 3 studies of baricitinib, a Janus kinase (JAK)1 and JAK2 inhibitor, in moderate to severe atopic dermatitis (AD).

Objective: To assess the efficacy and safety of baricitinib in adult moderate to severe AD.

Materials and Methods: BREEZE-AD1 and BREEZE-AD2 were identical randomized, double-blind, placebo-controlled phase 3 monotherapy trials. Randomization was 2:1:1:1 to placebo, baricitinib 1-mg, 2-mg, or 4-mg daily for 16 weeks. The primary endpoint was the proportion of patients achieving Validated Investigator's Global Assessment for AD score of 0 (clear) or 1 (almost clear) with a ≥2-point improvement from baseline at Week 16. Multiplicity-adjusted analyses were performed on primary and key secondary endpoints.

Results: Significantly more patients achieved the primary endpoint on baricitinib 4-mg and 2-mg compared to placebo in BREEZE-AD1 (N=624)/BREEZE-AD2 (N=615) (baricitinib 4-mg 16.8%/13.8% [$p<0.01$]; 2-mg 11.4%/10.6% [$p<0.05$]; and placebo 4.8%/4.5%, respectively). In both trials, significantly more patients achieved an Eczema Area and Severity Index (EASI)-75 on baricitinib 4-mg and 2-mg than placebo (baricitinib 4-mg 24.8%/21.1% [$p<0.05$]; 2-mg 18.7%/17.9% [$p<0.05$]; and placebo 8.8%/6.1%, respectively). Significant improvement in itch was achieved as early as Week 1 for 4-mg and Week 2 for 2-mg. Improvements in night time awakenings, skin pain, dermatology life quality index, and Patient-Oriented Eczema Measure were observed by Week 1 for both 4-mg and 2-mg. Pooled adverse events (AEs) were reported in 55%, 54%, 58%, and 56%, while serious AEs were reported in 3%, 4%, 1.2%, and 1.2% on placebo, 1-mg, 2-mg, and 4-mg, respectively. The most common adverse events were nasopharyngitis and headache. No venous thromboembolisms, major adverse cardiovascular events, or deaths were reported.

Conclusions: Treatment with baricitinib significantly improved the signs and symptoms of moderate to severe AD compared to placebo, and represents a potential novel treatment option.