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Impact of baricitinib on patient-reported skin symptoms, itch, and quality of life in adult patients with moderate to severe atopic dermatitis and an inadequate response to topical therapies from phase 3 trials BREEZE-AD1 and BREEZE-AD2

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Background: Baricitinib is an oral, selective inhibitor of Janus kinase (JAK) 1 and JAK2 under investigation for treatment of adult patients with moderate to severe atopic dermatitis (AD). Primary results of 2 phase 3 trials were disclosed elsewhere; the objective here is to report the trials' patient-reported secondary measures of skin symptoms, itch, and quality of life (QoL).

Methods: In identical, independent 16-week trials (BREEZE-AD1/BREEZE-AD2), patients were randomized (2:1:1:1) to placebo (AD1/AD2, n = 249/244, respectively), baricitinib 1 mg (127/125), 2 mg (123/123), or 4 mg daily (125/123). Measurements included the SCORing Atopic Dermatitis (SCORAD), Patient Global Impression of Severity (PGI-S-AD), and Dermatology Life Quality Index (DLQI). Outcomes were analyzed by logistic regression (categoric) and mixed model repeated measures (continuous).

Results: Baseline characteristics were similar between studies. At week 16, baricitinib-treated patients were significantly more likely than placebo-treated patients to improve by the SCORAD75 (AD1/AD2 respectively, placebo: 1%/2%; 1 mg: 6%/5%; 2 mg: 7%/7%; 4 mg: 10%/11%; $P \leq .01$, for 2 and 4 mg, both studies) and mean change in PGI-S-AD ($P \leq .001$, for 2 mg in AD2, and $P \leq .001$, for 4 mg, both studies). Baricitinib, versus placebo, resulted in significantly greater improvements in SCORAD pruritus scores at week 1 ($P \leq .01$ for 2 and 4 mg, both studies) and week 16 ($P \leq .01$ for 2 mg in AD2 and 4 mg, both studies), and greater likelihood to have DLQI 0/1 at week 16 (AD1/AD2 respectively, placebo: 5%/3%, 1 mg: 8%/10%; 2 mg: 11%/11%; 4 mg: 17%/15%; $P < .05$, for 2 and 4 mg, both studies).

Conclusions: Baricitinib demonstrated rapid onset of improvements in AD skin and pruritus severity and clinically meaningful improvements in QoL.

Commercial disclosure: 100% sponsored by Eli Lilly and Co.

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Safety of baricitinib in patients with atopic dermatitis: Results of pooled data from two phase 3 monotherapy randomized, double-blind, placebo-controlled 16-week trials (BREEZE-AD1 and BREEZE-AD2)

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Background: We assessed safety of patients with AD from two phase 3 studies of baricitinib (BREEZE-AD1 [NCT03334396] and BREEZE-AD2 [NCT03334422]).

Methods: BREEZE-AD1/BREEZE-AD2 were double-blind, placebo-controlled monotherapy trials (randomization [2:1:1:1] to placebo, baricitinib 1-mg, 2-mg or 4-mg daily for 16 weeks). Safety data were pooled from both studies and analyzed for all patients who received ≥1 dose of study drug.

Results: Results are presented for placebo, baricitinib 1 mg, 2 mg, and 4 mg groups, respectively. Treatment emergent adverse events were reported in 55.2%, 53.8%, 57.7%, and 56.0%, and serious AEs in 3.0%, 4.0%, 1.2%, and 1.2% of patients. Frequency of infections was similar across groups (30.4%, 30.7%, 34.1%, and 33.9%) with few (≤2%) eczema herpeticum (EH), herpes zoster or serious infections, and no opportunistic infections or tuberculosis. Herpes simplex rates were 2.8%, 5.2%, 4.5%, and 5.6% including EH; serious EH events were reported in placebo (n = 2) and 1 mg (n = 2) only. No venous thromboembolisms, major adverse cardiovascular events, or deaths were reported. Grades 3/4 CPK elevations were seen in 2.0%, 2.0%, 2.4%, and 3.6%, patients. No clinically meaningful changes in hemoglobin, neutrophil, lymphocytes, or IgE levels were observed. Rates of thrombocytosis were 0, 0.8%, 1.6%, and 0.4%. No patients had hemoglobin or neutrophil increases to CTCAE grades 3/4; 1 patient (1 mg) had lymphocyte increase to grade 3. Eosinophils increased in 23.8% of placebo vs baricitinib 1 mg (26.7%), 2 mg (17.2%) or 4 mg (18.5%).

Conclusions: Baricitinib in AD was generally safe and well tolerated through 16 weeks. The full safety profile should be confirmed with longer-term safety data.

Commercial disclosure: 100% sponsored by Eli Lilly and Company.

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Baricitinib, an oral reversible Janus kinase 1 and 2 inhibitor, for atopic dermatitis: Head and neck response across two phase 3 studies

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Background: In adults with atopic dermatitis (AD), head and/or neck involvement is frequent, bothersome, and impacts quality of life; however, topical corticoid steroids are contraindicated for this difficult-to-treat region. In 2 phase 3 trials of baricitinib for AD, at baseline 98.1% (n = 1215) of patients had head/neck Eczema Severity and Area Index (EASI) > 0. We report treatment efficacy in this population.

Methods: Data were combined from BREEZE-AD1 (NCT03334396, n = 624) and BREEZE-AD2 (NCT03334422, n = 615), which were double-blind trials (randomization 2:1:1:1 placebo, baricitinib 1 mg, 2 mg, or 4 mg daily for 16 weeks). Analyses were performed using mixed model repeated measure (EASI percent change) or logistic regression (EASI50 responder).

Results: Patients were 38% female; overall median age was 33 years. Mean baseline scores were 32.2 EASI and 31.7 EASI head/neck subscore (mean extent 54.8%; mean erythema 2.3). At week 1, mean EASI improvement was 8.9% placebo, 24.1% BARI 2-mg, and 28.6% BARI 4-mg ($P < .001$, each BARI group vs placebo) with a 5.3%, 18.2%, and 23.0% improvement in head/neck area, respectively ($P < .001$, each BARI group vs placebo). Proportions of patients achieving EASI50 for head/neck region at week 16 were higher with baricitinib (25.6% 2 mg and 31.9% 4 mg) vs placebo (13.8%; $P < .001$, both comparisons). Proportions of patients with 50% improvement in the head/neck erythema score from EASI were higher with baricitinib at week 1 ($P < .001$, each BARI group vs placebo) and week 16 ($P < .01$, each BARI group vs placebo).

Conclusions: Baricitinib 2-mg and 4-mg treatment showed rapid and substantial improvements in AD head and neck severity, including erythema.

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Association of psoriasis with inflammatory bowel disease: A retrospective study

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Psoriasis is a chronic inflammatory disease characterized by localized or widespread silvery, scaly, and erythematous plaques distributed symmetrically. Several studies have demonstrated the association of psoriasis with inflammatory bowel disease (IBD). IBD comprises two principle phenotypes, Crohn disease (CD) and ulcerative colitis (UC). The prevalence and relative risk of IBD in psoriatic patients and in those with psoriatic arthritis (PsA) are higher than in the general population. This study aims to determine IBD prevalence in patients with psoriasis while correlating IBD with psoriasis phenotype. A retrospective cohort study was performed reviewing charts at the University of Puerto Rico Dermatology Clinics from January 2016 to March 2019. The following were assessed: demographics, past medical history, age at IBD diagnosis, treatment, and PsA. Total number of patients with psoriasis was 719 of which 9 (1.12%) had IBD with a mean age at diagnosis of thirty; 33% (3) had Crohn disease, and 67% (6) had ulcerative colitis. PsA was observed in 33% of patients with concomitant IBD and psoriasis. Prevalence of PsA, rheumatoid arthritis, diabetes mellitus, and hypercholesterolemia did not differ between IBD and non-IBD groups. Our study showed that 67% of patients who developed IBD presented with mild psoriasis, whereas 62% of patients with psoriasis without IBD presented with severe psoriasis. Biologic treatment for psoriasis correlated with fewer IBD symptoms. Our study compares to other studies and makes us consider implementing biologic treatment for psoriasis earlier in the course to prevent other inflammatory diseases such as IBD.

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