Effect of upadacitinib on SCORAD intensity items: Analysis from the Measure Up 1 and Measure Up 2 studies

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Introduction/Background: Atopic dermatitis (AD) is a chronic, inflammatory disease characterized by typical clinical signs (erythema, edema/papulation, oozing/crusting, excoriation, lichenification, and dryness) and prominent itch that can markedly impact a patient’s sleep and quality of life (QoL). Upadacitinib is a selective oral Janus kinase (JAK) inhibitor with greater inhibitory potency for JAK1 vs JAK2, JAK3, and tyrosine kinase 2. The SCORing Atopic Dermatitis (SCORAD) measure is a validated assessment tool that evaluates the extent of disease based on the area of the body affected, intensity of clinical signs of AD, and itch and sleeplessness due to AD.

Objectives: In this integrated post hoc analysis of the Measure Up 1 and Measure Up 2 studies, we compared the effects of upadacitinib (15 mg and 30 mg) versus placebo on the intensity of the individual signs assessed by the SCORAD at week 2 and week 16.

Methods: Measure Up 1 and 2 are replicate phase 3 multicenter, randomized, double-blind studies comparing the safety and efficacy of upadacitinib 15 mg and upadacitinib 30 mg to placebo in adolescent and adult patients with moderate-to-severe AD. Patients were randomized to upadacitinib 15 mg, upadacitinib 30 mg, or placebo orally once daily. All patients received additive-free, bland emollient twice daily for at least 7 days before baseline and during the study until week 16. The current study assessed the intensity of the six clinical signs assessed by the SCORAD (erythema, edema/papulation, oozing/crusting, excoriation, lichenification, and dryness with a 4-level rating scale of none, mild, moderate, and severe). The proportions of patients achieving resolution (i.e., an intensity rating of “none”) of each clinical sign at week 2 and week 16 were evaluated among patients with mild, moderate, or severe intensity at baseline. Resolution rates were compared using the Mantel-Haenszel test. Missing data were handled using non-responder imputation.

Results: A total of 1679 participants (placebo, 558; upadacitinib 15 mg, 557; upadacitinib 30 mg, 564) were included in the analysis of integrated data from the Measure Up 1 and Measure Up 2 studies. Differences in the proportion of patients achieving resolution for both upadacitinib doses (15 mg/30 mg) versus placebo were observed at week 2 (p<0.0001) for: erythema (3.1%/6.0% vs. 0.0%); edema/papulation (13.1%/16.6% vs 1.3%); oozing/crusting (49.8%/59.1% vs 15.6%); excoriation (26.9%/34.6% vs 3.1%); lichenification (9.6%/13.5% vs 1.4%); and dryness (8.6%/11.9% vs 1.8%). Resolution rates were also higher with upadacitinib (15 mg/30 mg) versus placebo at week 16 (p<0.0001) for: erythema (22.2%/29.7% vs. 2.2%);
edema/papulation (33.6%/42.8% vs 4.9%); oozing/crusting (62.1%/72.0% vs 20.5%); excoriation (43.3%/54.6% vs 8.5%); lichenification (30.8%/40.7% vs 5.2%); and dryness (28.7%/35.9% vs 4.4%).

**Conclusions:** Greater proportions of patients treated with upadacitinib 15 mg or upadacitinib 30 mg achieved resolution of erythema, edema/papulation, oozing/crusting, excoriation, lichenification, or dryness compared to placebo at week 2 and week 16. Complete resolution of these clinical signs of AD may correspond to reductions in disease burden that translate to improved QoL. Consideration of the clinical signs of AD as assessed by the SCORAD may help inform physicians as they tailor their treatment choices specifically to the unique skin manifestations of each individual patient.

**Keywords:** upadacitinib, atopic dermatitis, SCORAD intensity scores

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