Rapid and Durable Skin Pain Relief with Upadacitinib in Adults and Adolescents with Moderate-to-Severe Atopic Dermatitis

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OBJECTIVE

To evaluate the efficacy of upadacitinib (UPA) in reducing skin pain in adults and adolescents with moderate-to-severe atopic dermatitis (AD)

CONCLUSIONS

Rapid skin pain relief was reported in patients with moderate-to-severe AD as early as Day 2 (24 hours after treatment initiation) when treated with UPA 15mg (UPA15) or UPA 30mg (UPA30) monotherapy once daily

The achievement of an optimal target of skin pain relief (Skin Pain [SP] Numerical Rating Scale [SP-NRS] 0/1) was largely maintained through Week 140

Reduction of skin pain was associated with improvements in patient-reported outcomes (PROs) including sleep, daily activities, and emotional state

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SYNOPSIS

- Itch, skin pain, and eczematous lesions are characteristic features of AD[1]
- Skin pain is increasingly recognized as a common and burdensome symptom of AD, reported by 61% of patients in a cross-sectional, US population survey-based study of adults with AD, that can impair daily activities, sleep, and mental health[2]
- UPA is an oral selective Janus kinase 1 (JAK-1) inhibitor approved for treatment of AD and other chronic inflammatory conditions
- This study evaluated the efficacy of UPA in reducing skin pain and the meaning of achieving no or minimal skin pain in adults and adolescents with moderate-to-severe AD

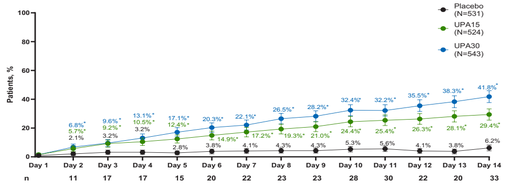
METHODS

- This analysis assessed integrated data from adults and adolescents with moderate-to-severe AD treated with UPA monotherapy in two studies: Measure Up 1 (NCT03569293) and Measure Up 2 (NCT03607422)
- Patients were randomized to receive UPA15, UPA30, or placebo for 16 weeks in the double-blind, placebo-controlled period
  - At Week 16, patients randomized to UPA groups continued treatment, and placebo groups were re-randomized to UPA15 or UPA30 for the double-blind, long-term extension period
- Skin pain (SP) was evaluated using the Atopic Dermatitis Symptom Scale (ADerm-SS) Skin Pain Numerical Rating Scale (SP-NRS; range: 0-10)[3]
- The optimal outcome was defined as an SP-NRS of 0 or 1, corresponding to no or minimal skin pain; the moderate target for skin pain was defined as clinically meaningful improvement (SP-NRS improvement by 3 or more points)[4]
  - Response rates were based on non-responder imputation (NRI) through Week 16 and observed cases (OC) through Week 140
- Among patients who achieved SP-NRS of 0/1 at Week 16, long-term maintenance of response was evaluated through Week 140
- Patient-reported impacts on sleep, daily activities, and emotional state were assessed by the Atopic Dermatitis Impact Scale (ADerm-IS) Item 2 Sleep NRS (range: 0-10), Daily Activities domain (range: 0-40), and Emotional State domain (range: 0-30), respectively; no/minimal impact of AD was defined as scores of 0-1 (Sleep) or 0-2 (Daily Activities and Emotional State)

RESULTS

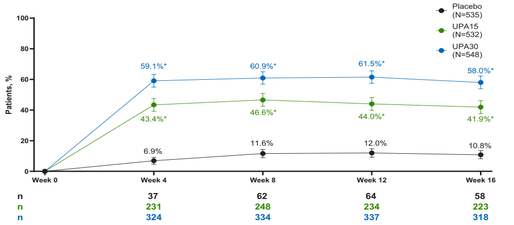
- At baseline, 85% of trial patients reported skin pain (SP-NRS ≥4)
- Compared with placebo (n=531), patients treated with UPA15 (n=524) and UPA30 (n=543) achieved higher rates of SP-NRS 0/1 as early as Day 2 (the day after treatment initiation) (Figure 1), with response rates increasing through Week 4 (UPA15: 43.4%; UPA30: 59.1%; both p<0.05) (Figure 2)
- Response rates were sustained through Week 140 in the overall population (UPA15: 63.8%; UPA30: 72.3%; OC) (Figure 3) and among patients who achieved SP-NRS 0/1 at Week 16 (UPA15: 78.9%; Figure 4A) (UPA30: 83.0%; Figure 4B)
- Achieving SP-NRS 0/1 was associated with substantially higher proportions of patients reporting optimal sleep quality, daily functioning, and overall quality-of-life outcomes at Week 16 (Figure 5)

Figure 1. Rapid Achievement of Daily Skin Pain 0/1 through Day 14 (NRI-NC)



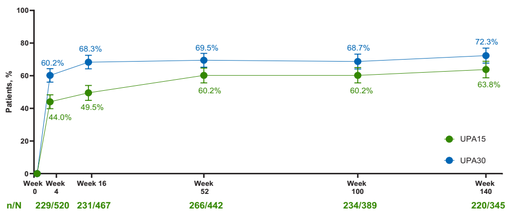
Note: NRI-NC is non-responder imputations with no special data handling for missing due to COVID-19. * p<0.05. Day 1 to 14 among patients with SP-NRS >1 at Baseline. Baseline refers to the last available daily assessment before the date of first administration of study drug. Bars represent 95% confidence interval (CI) based on the normal approximation to the binomial distribution. P-values are calculated according to the Cochran-Mantel-Haenszel test adjusted for strata (study, baseline validated Investigator's Global Assessment-AD categories, age [adolescent vs adult]).

Figure 2. Rapid Achievement of Weekly Skin Pain 0/1 through Week 16 (NRI-C)



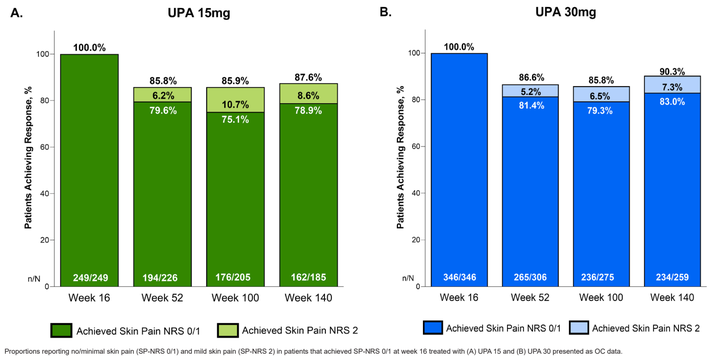
Note: NRI-C is non-responder imputation incorporating multiple imputation to handle missing data due to COVID-19. * p<0.05. Week 4 to Week 16 among patients with SP-NRS >1 at Baseline. Baseline refers to the last available daily assessment before the date of first administration of study drug. Bars represent 95% confidence interval (CI) based on the normal approximation to the binomial distribution. P-values are calculated according to the Cochran-Mantel-Haenszel test adjusted for strata.

Figure 3. Long-Term Achievement of Weekly Skin Pain 0/1 through Week 140 (OC)



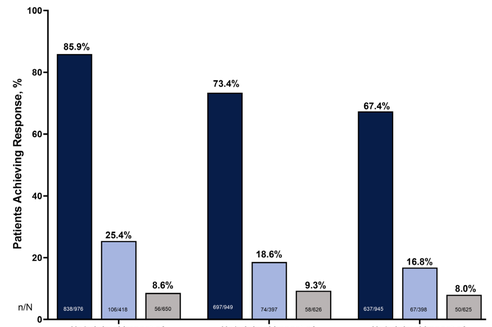
Percentage of patients achieving SP-NRS of 0/1 for patients with SP-NRS >1 at Baseline by visit. Baseline refers to last available rolling average before the date of first administration of the study drug. Bars represent 95% CI based on the normal approximation to the binomial distribution.

Figure 4. Long-Term Maintenance of Skin Pain Relief Through Week 140 Among Week 16 Optimal Achievers



Proportions reporting no/minimal skin pain (SP-NRS 0/1) and mild skin pain (SP-NRS 2) in patients that achieved SP-NRS 0/1 at week 16 treated with (A) UPA 15 and (B) UPA 30 presented as OC data.

Figure 5. Achievement of Other PROs in Relation to Achievement of Optimal Skin Pain Outcomes at Week 16



No/minimal impact of AD on sleep defined as Sleep NRS 0/1. No/minimal impact of AD on daily activities defined as ADerm-IS Daily Activities 0-2. No/minimal impact of AD on emotional state defined as ADerm-IS Emotional State 0-2. Abbreviations: ADerm-IS, Atopic Dermatitis Index Scale; NRS, Numerical Rating Score.

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