Rapid Itch Relief with Upadacitinib vs Dupilumab in Adults and Adolescents with Moderate-to-Severe Atopic Dermatitis: Results from the Phase 3b/4 Level Up Study

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OBJECTIVE

Compare itch improvement in patients with atopic dermatitis treated with upadacitinib versus dupilumab

CONCLUSIONS

Within days following treatment initiation, a higher proportion of patients receiving UPA achieved clinically meaningful itch improvement and minimal-to-no itch than patients receiving DUPI

Response with UPA was rapid, with the efficacy rates observed with DUPI at day 28 attained at day 10 (ΔWP-NRS ≥4) and day 9 (WP-NRS 0/1) with UPA

These data can help inform shared decision-making discussions among patients with AD seeking rapid itch relief

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INTRODUCTION

- Atopic dermatitis (AD) is a chronic inflammatory condition often presenting with an itchy, scaly rash
- Patients report itch as their most problematic symptom leading to reduced health related quality of life emphasizing the need for rapid itch relief[1]
- Here we assess rapid (<28 day) itch improvement in patients with atopic dermatitis treated with upadacitinib (UPA - selective oral Janus kinase inhibitor) versus dupilumab (DUPI - interleukin 4 and 13 signaling inhibitor) in the Level Up study
  - Level Up Period 1 and Period 2 results have been previously presented[2,3,4]

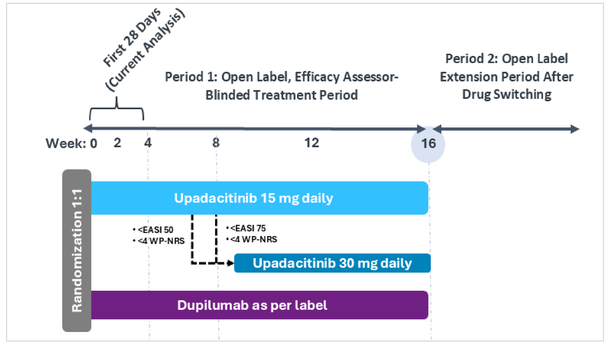
METHODS

- Level Up (NCT05601882) is a Phase 3b/4 global, randomized, open-label, efficacy assessor blinded, head-to-head multi-center study evaluating UPA vs DUPI in patients aged ≥12 years to <64 years with moderate-to-severe AD with an inadequate response to systemic therapy or when those therapies were inadvisable
- During the first 28 days of period 1, patients were randomized 1:1 to receive UPA 15 mg once daily or DUPI per label

METHODS CONTINUED

- In the first 28 days, the following outcomes were evaluated:
  - **Meaningful itch improvement:** Worst Pruritus Numerical Rating Scale (WP-NRS) improvement ≥4 from Baseline among patients with WP-NRS ≥4 at Baseline (ΔWP-NRS ≥4)
  - **Little-to-no itch:** WP-NRS of 0 or 1 among patients with WP-NRS >1 at Baseline (WP-NRS 0/1)
- Results are reported using non-responder imputation with P-values from Mantel-Haenszel test adjusting for age and baseline vIGA-AD
- Safety and demographics have been previously published[2]

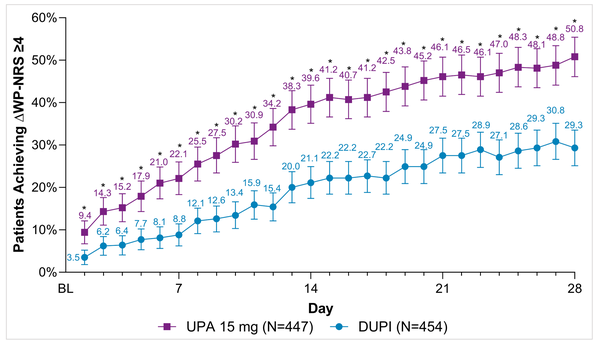
Figure 1. Study Design



RESULTS

- Beginning at day 2 (the day after initiating treatment), a higher proportion of patients receiving UPA, compared to DUPI, achieved clinically meaningful reduction in itch
- This trend continued daily, with more than half of UPA-treated patients (50.8%) achieving clinically meaningful itch improvement by day 28
- At day 28, 29.3% of DUPI-treated patients achieved clinically meaningful itch improvement; this response rate was attained with UPA 18 days prior (day 10, 30.2%)
- Beginning at day 4 (3 days after treatment initiation), a higher proportion of patients receiving UPA compared to DUPI achieved little-to-no itch
- This trend continued daily with 18.9% of UPA-treated patients achieving little-to-no-itch by day 28
- At day 28, 5.7% of DUPI-treated patients achieved little-to-no-itch; this response rate was attained with UPA 19 days prior (day 9, 6.6%)

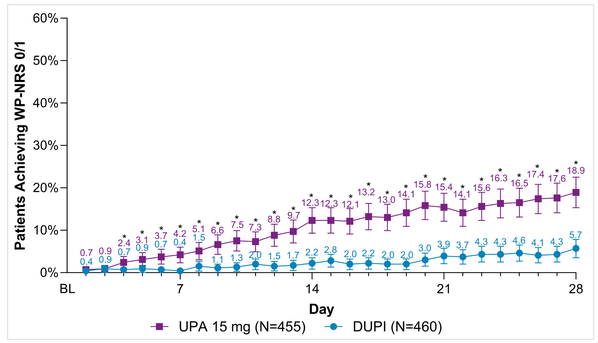
Figure 2. Proportion of Patients Achieving Meaningful Itch Improvement (ΔWP-NRS ≥4)



Data reported by non-responder imputation
DUPI, dupilumab; UPA, upadacitinib; WP-NRS, Worst Pruritus Numerical Rating Scale; ΔWP-NRS ≥4, WP-NRS improvement ≥4 from baseline among patients with WP-NRS ≥4 at Baseline

* Nominal p value <0.05 UPA vs DUPI

Figure 3. Proportion of Patients Achieving Minimal-to-no Itch (WP-NRS 0/1)



* Nominal p value <0.05 UPA vs DUPI
Assessed in patients with baseline WP-NRS ≥ 1 at baseline using non-responder imputation
DUPI, dupilumab; UPA, upadacitinib; WP-NRS, Worst Pruritus Numerical Rating Scale