Efficacy of Upadacitinib vs Dupilumab Treatment for Moderate-to-Severe Atopic Dermatitis: Analysis of Time Spent in Response State From the Level Up Study

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OBJECTIVE

To evaluate the time spent in Eczema Area and Severity Index 90 and/or Worst Pruritus Numerical Rating Scale score of 0/1 response states in patients receiving upadacitinib or dupilumab over a 16-week period

CONCLUSIONS

Treatment of moderate-to-severe atopic dermatitis with upadacitinib per label resulted in a greater number and proportion of days spent with Eczema Area and Severity Index 90 and/or Worst Pruritus Numerical Rating Scale score of 0/1 compared with dupilumab over 16 weeks

These results highlight differences in lived day-to-day state of clear/nearly-clear skin and/or no/minimal itch over the course of treatment and can be used to inform shared decision-making discussions between patients and physicians

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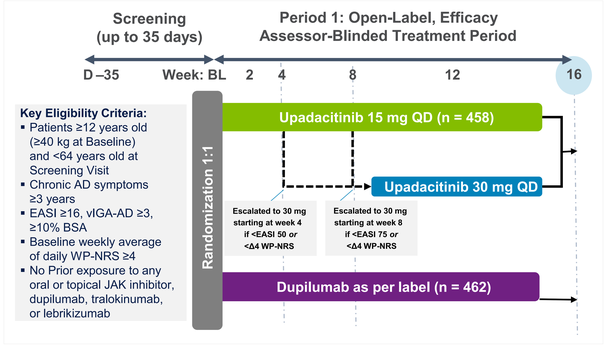
INTRODUCTION

- Atopic dermatitis (AD) is a chronic, inflammatory skin disease characterized by intense pruritus and skin lesions. Upadacitinib (UPA), a selective oral Janus kinase (JAK) inhibitor, and dupilumab (DUPI), a monoclonal antibody targeting interleukin-4Rα, are both treatments approved for patients with moderate-to-severe AD
- Results from a phase 3b/4 trial (Level Up) indicated that UPA was superior to DUPI in simultaneously achieving the stringent endpoints of Eczema Area and Severity Index (EASI) improvement of ≥90% from baseline (EASI 90) and a Worst Pruritus Numerical Rating Scale score of 0/1 (WP-NRS 0/1),[1] one of the definitions of Minimal Disease Activity (MDA),[2] at week 16. Safety data from this trial has been previously reported[1]
- While most clinical trials adopted efficacy endpoints at single timepoints; analyses of the time spent with/without symptoms of AD may be more reflective of the cumulative, debilitating nature of AD and its negative impacts on quality of life

METHODS

- The Level Up (NCT05601882) study was a phase 3b/4 head-to-head global, randomized, open-label, efficacy assessor blinded, multicenter study comparing UPA vs DUPI as monotherapies in adolescents and adults with moderate-to-severe AD **(Figure 1)**
- The current analyses assessed the number and proportion of days patients spent with clear or nearly-clear skin (EASI 90) and/or no/minimal itch (WP-NRS 0/1), with comparisons made at the median (50th percentile) and upper quartile (eg, 75th percentile). Results are based on nonresponder imputation with multiple imputation **(NRI-MI)**

Figure 1. Level Up Study Design (Period 1)



EASI, Eczema Area and Severity Index; JAK, Janus kinase; MDA, Minimal Disease Activity; vIGA-AD, validated Investigator Global Assessment for Atopic Dermatitis; WP-NRS 01, Worst Pruritus Numerical Rating Scale score of 0/1.
Starting at week 4, rescue with topical therapy was optional and per investigator's discretion if protocol criteria were met.

RESULTS

- Superior EASI 90, WP-NRS 0/1, and MDA response rates were achieved with UPA vs DUPI over the 16-week period **(Figures 2–4)**[1]
- Distribution of the times spent in an EASI 90, WP-NRS 0/1, and MDA response state were skewed as evidenced by differences in mean and median values, reflecting the stringency of the assessed individual and combined (MDA) endpoints **(Table 1)**
- Compared to DUPI patients, UPA patients spent a greater cumulative number and proportion of days in EASI 90 and WP-NRS 0 or 1 response states from the 50th to 99th percentiles (nominal *P* values <.01), and in MDA from the 75th to 99th percentiles (**Figures 5–7**; nominal *P* values <.0001)

Table 1. Mean and Median Proportion of Days and Cumulative Days Spent at EASI 90, WP-NRS 0/1, and MDA Through Week 16

		Proportion of Days		Cumulative Days	
	N	Mean (SE)	Median (SE)	Mean (SE)	Median (SE)
EASI 90					
DUPI	462	14.1% (1.41%)	0.0% (4.15%)	16.0 (1.61)	0.0 (4.64)
UPA	458	29.4% (1.42%)	24.8% (3.96%)	33.5 (1.62)	28.0 (4.42)
WP-NRS 0/1					
DUPI	460	11.5% (1.34%)	0.4% (0.89%)	12.8 (1.49)	0.4 (1.00)
UPA	455	26.1% (1.34%)	10.1% (2.66%)	29.1 (1.50)	11.3 (2.96)
MDA					
DUPI	460	4.2% (0.92%)	0.0 (NE)	4.7 (1.02)	0.0 (NE)
UPA	455	14.0% (0.92%)	0.0 (NE)	15.6 (1.03)	0.0 (NE)

DUPI, dupilumab; EASI, Eczema Area and Severity Index; MDA, Minimal Disease Activity; NE, not estimable; UPA, upadacitinib; vIGA-AD, validated Investigator Global Assessment for Atopic Dermatitis; WP-NRS 01, Worst Pruritus Numerical Rating Scale score of 0/1.
Means (ANOVA), medians (quantile regression), and standard errors (SE) are based on models with effects for treatment, age, and baseline vIGA-AD.

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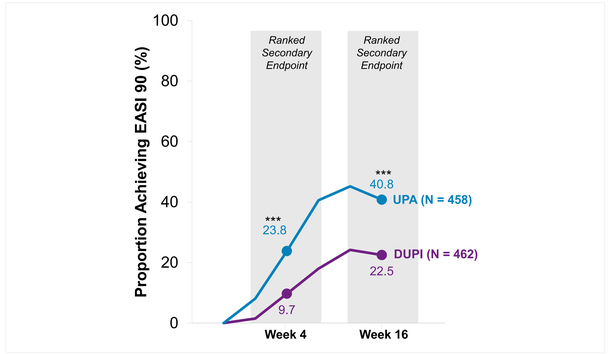
B. Duarte has participated in advisory boards and/or been a speaker for AbbVie, Almirall, J&J, LEO, Lilly, Pfizer, and Sanofi-Genzyme. R. Chovatiya has served as an advisor, consultant, speaker, and/or investigator for AbbVie, Amgen, Anaptysbio, Apogee, Arcutis, Argenx, Beiersdorf, BI, BMS, Cara, CLn Skin Care, Dermavant, EMD Serono, FIDE, Formation Bio, Galderma, Genentech, GSK, J&J, Incyte, LEO, Lilly, L'Oréal, Nektar, Novartis, Opsidio, Pfizer, RAPT, Regeneron, Sanofi, Sitryx, Takeda, Thx Bio, and UCB. D. Thaçi is an advisor, speaker, or consultant for AbbVie, Almirall, Amgen, BI, BMS, Celltrion, Galderma, Janssen, Kyowa Kirin, LEO, Lilly, L'Oréal, New Bridge, Novartis, Pfizer, Regeneron, Sanofi-Genzyme, Target RWE, UCB, and Vichy. V. Shi is a stock shareholder of Learn Health and has served as an advisory board member, investigator, speaker, and/or received research funding from AbbVie, Almirall, Altus Labs/Quell, Alumis, Aristea, Bain Capital, BI, Burt's Bees, Castle, Ceraderm, Dermavant, Dermira, Galderma, Genentech, GpSkin, Incyte, Kiniksa, LEO, Lilly, Mento, MYOR, Novartis, Pfizer, Polyfins Technology, Regeneron, Sanofi-Genzyme, Skin Actives Scientific, Sun, Target-PharmaSolutions, and UCB. B. Yang no conflicts reported. J. Talia has served as a consultant and/or investigator for AbbVie, Arcutis, BMS, Callistbas, Galderma, J&J, LEO A/S, Navigator Medicines, Novartis, Primus, Provaxt, Sanofi-Genzyme, Stiftel Financial, and UCB. D. Prefontaine, V. Punia, A. Pechonkina, M. Lane, and B.M. Calimlim are full-time employees of AbbVie Inc. and may hold AbbVie stock and/or stock options. J.I. Silverberg has received consulting fees from and/or served as an investigator for AbbVie, Anacor, Celgene, GSK, Lilly, MedImmune, P&G, Pfizer, Regeneron, and Roche.

RESULTS CONTINUED

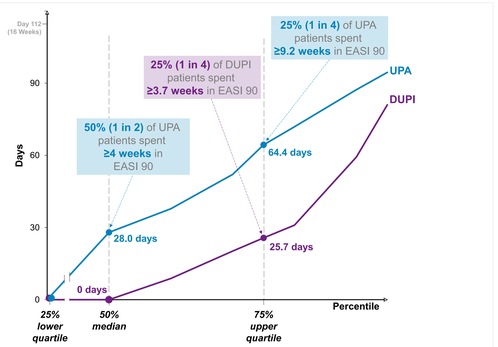
EASI 90

Figure 2. EASI 90 Response Rate



DUPI, dupilumab; EASI, Eczema Area and Severity Index; UPA, upadacitinib.
Starting at week 4, rescue with topical therapy was optional and per investigator's discretion if protocol criteria were met.

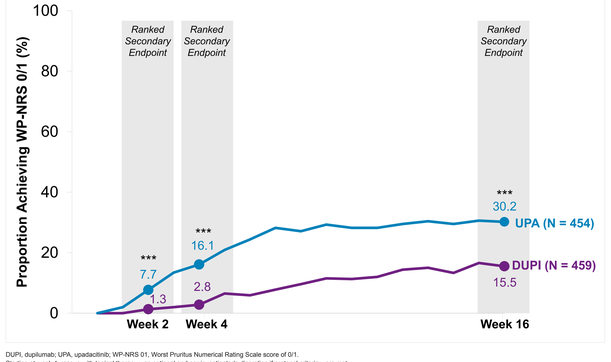
Figure 5. Cumulative Days Spent at EASI 90 Through Week 16 (112 days)



DUPI, dupilumab; EASI, Eczema Area and Severity Index; UPA, upadacitinib.
Starting at week 4, rescue with topical therapy was optional and per investigator's discretion if protocol criteria were met.

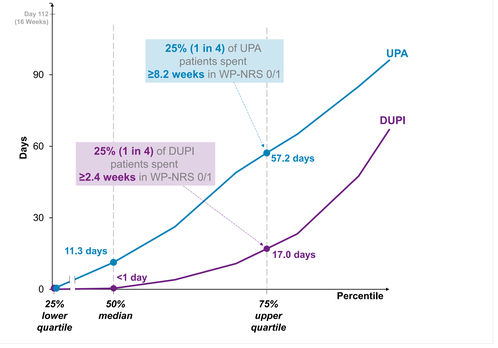
WP-NRS 0/1

Figure 3. WP-NRS 0/1 Response Rate



DUPI, dupilumab; UPA, upadacitinib; WP-NRS 01, Worst Pruritus Numerical Rating Scale score of 0/1.
Starting at week 4, rescue with topical therapy was optional and per investigator's discretion if protocol criteria were met.

Figure 6. Cumulative Days Spent at WP-NRS 0/1 Through Week 16 (112 days)



DUPI, dupilumab; UPA, upadacitinib; WP-NRS 01, Worst Pruritus Numerical Rating Scale score of 0/1.
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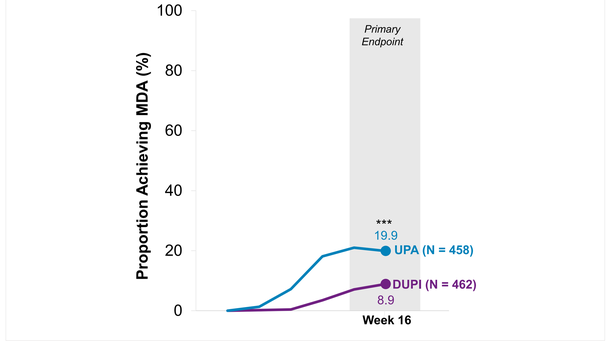
MDA (EASI 90 & WP-NRS 0/1)

Figure 4. MDA Response Rate



DUPI, dupilumab; EASI, Eczema Area and Severity Index; MDA, Minimal Disease Activity; UPA, upadacitinib; WP-NRS 01, Worst Pruritus Numerical Rating Scale score of 0/1.
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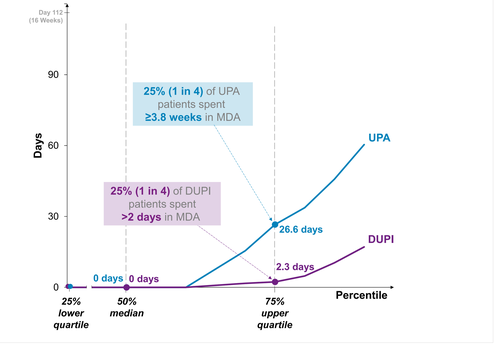
Figure 7. Cumulative Days Spent at MDA Through Week 16 (112 days)



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