Long-Term Maintenance of Optimal Treatment Targets for Skin and Itch Outcomes With Upadacitinib in Moderate-to-Severe Atopic Dermatitis: 140-Week Results From the Phase 3 Measure Up 1 and 2 Studies

Naiem T. Issa,[1–4] Raj Chovatiya,[5,6] Jordan Talia,[7] Tiago Torres,[8,9] Killian Eyerich,[10] Brian M. Calimlim,[11] Yang Yang,[11] Alena Pechonkina,[11] Alvaro Moreira,[11] Ayman Grada,[11] Christopher G. Bunick[12]

[1]Department of Dermatology and Cutaneous Surgery, University of Miami Leonard M. Miller School of Medicine, Miami, FL, USA; [2]Forefront Dermatology, Vienna, VA, USA; [3]Issa Research and Consulting, LLC, Springfield, VA, USA; [4]Department of Dermatology, George Washington University School of Medicine and Health Sciences, Washington, DC, USA; [5]Chicago Medical School, Rosalind Franklin University of Medicine and Science, North Chicago, IL, USA; [6]Center for Medical Dermatology and Immunology Research, Chicago, IL, USA; [7]Department of Dermatology, Icahn School of Medicine at Mount Sinai, New York, NY, USA; [8]Department of Dermatology, Unidade Local de Saúde de Santo António, Porto, Portugal; [9]Instituto de Ciências Biomédicas Abel Salazar, University of Porto, Porto, Portugal; [10]Department of Dermatology, University of Freiburg, Freiburg im Breisgau, Germany; [11]AbbVie Inc., North Chicago, IL, USA; [12]Department of Dermatology and Program in Translational Biomedicine, Yale School of Medicine, New Haven, CT, USA

OBJECTIVE

To evaluate the long-term maintenance of optimal skin and itch treatment targets from week 16 through week 140 in patients with atopic dermatitis receiving upadacitinib therapy

CONCLUSIONS

Most patients achieved and maintained optimal treatment targets and minimal disease activity for atopic dermatitis through 140 weeks of upadacitinib treatment

Among patients who did not maintain optimal outcomes, the majority still maintained a clinically meaningful response

These findings underscore the potential for patients to achieve and maintain optimal treatment targets with upadacitinib, providing sustained long-term disease control that may translate into a more stable and predictable treatment experience, ultimately elevating the standard of care for patients with atopic dermatitis

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BACKGROUND

- Many patients with atopic dermatitis do not achieve optimal skin clearance and itch relief, even when undergoing prolonged systemic therapy[1,2]
- Optimal treatment targets, as defined by **A**iming **H**igh in **E**czema/**A**topic **D**ermatitis (AHEAD) guidelines, are recommended for disease control and improved patient outcomes in atopic dermatitis[1]
- AHEAD guidelines define minimal disease activity as the achievement of clinician- and patient-reported optimal treatment targets, such as ≥90% improvement from baseline in Eczema Area and Severity Index (EASI 90) and Worst Pruritus Numerical Rating Scale (WP-NRS) score of 0 or 1 (no/minimal itch)[1]
- Upadacitinib is an oral selective Janus kinase inhibitor approved for the treatment of moderate-to-severe atopic dermatitis in adolescents and adults[3]
- We evaluated the long-term maintenance of optimal treatment targets in atopic dermatitis with upadacitinib therapy among patients in the Measure Up 1 and Measure Up 2 phase 3 studies

METHODS

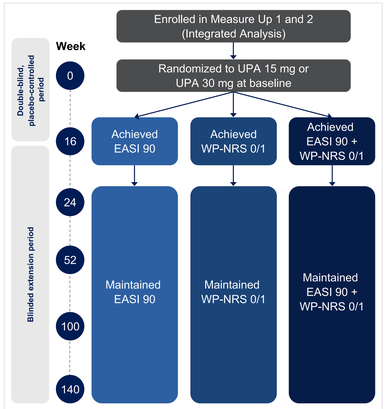
Study Design, Patients, and Treatment

- Measure Up 1 (NCT03569293) and Measure Up 2 (NCT03607422) are ongoing, phase 3, randomized, double-blind studies evaluating the efficacy and safety of upadacitinib in adolescents and adults with moderate-to-severe atopic dermatitis[4]
- Patients were randomized 1:1:1 at baseline to receive once-daily orally administered upadacitinib 15 mg, upadacitinib 30 mg, or placebo
- At week 16, patients initially randomized to receive placebo were rerandomized 1:1 to upadacitinib 15 mg or upadacitinib 30 mg, and patients initially randomized to either upadacitinib dose continued their assigned treatment
- This analysis included patients who were randomized to upadacitinib at baseline and continued upadacitinib treatment through week 140

Assessments and Statistical Analysis

- Assessed outcomes included maintenance of 3 optimal treatment targets from week 16 (end of the double-blind, placebo-controlled period) at weeks 24, 52, 100, and 140 (blinded extension period; **Figure 1**):
  - EASI 90 among patients who achieved EASI 90 at week 16
  - WP-NRS 0/1 among patients who achieved WP-NRS 0/1 at week 16
  - Simultaneous EASI 90 + WP-NRS 0/1 responses among patients who simultaneously achieved EASI 90 + WP-NRS 0/1 at week 16
- The long-term safety of upadacitinib has been reported elsewhere[5]
- Data from Measure Up 1 and Measure Up 2 were integrated for analysis and reported as observed cases with no imputation for missing data

Figure 1. Assessments for Long-Term Maintenance of Optimal Treatment Targets With Upadacitinib in the Measure Up 1 and 2 Studies



EASI 90, ≥90% improvement from baseline in Eczema Area and Severity Index; UPA, upadacitinib; WP-NRS 0/1, Worst Pruritus Numerical Rating Scale score of 0 or 1 (no/minimal itch) among patients with WP-NRS >1 at baseline.

RESULTS

Patients

- Baseline demographics and disease characteristics of the 1213 patients included in the analysis were well balanced across upadacitinib treatment groups **(Table 1)**

Table 1. Patient Demographics and Baseline Clinical Characteristics

Characteristic	UPA 15 mg (N = 603)	UPA 30 mg (N = 610)
Age, years, mean (SD)	32.3 (15.9)	32.6 (16.0)
Female, n (%)	277 (45.9)	269 (44.1)
Race, n (%)		
White	399 (66.2)	425 (69.7)
Asian	136 (22.6)	138 (22.6)
Black	47 (7.8)	27 (4.4)
Other[a]	9 (1.5)	3 (0.5)
Multiple	12 (2.0)	17 (2.8)
Weight, kg, mean (SD)	73.0 (18.9)	73.5 (18.2)
BMI, kg/m^2, mean (SD)	25.6 (5.8)	25.6 (5.7)
vIGA-AD, n (%)		
3 (moderate)	303 (50.2)	303 (49.7)
4 (severe)	300 (49.8)	307 (50.3)
EASI, mean (SD)	29.5 (12.2)	29.5 (11.8)
WP-NRS weekly average, mean (SD)	7.2 (1.6)	7.3 (1.6)

BMI, body mass index; EASI, Eczema Area and Severity Index; UPA, upadacitinib; vIGA-AD, validated Investigator's Global Assessment for Atopic Dermatitis; WP-NRS, Worst Pruritus Numerical Rating Scale.
[a]Includes American Indian/Alaska Native, Native Hawaiian or Other Pacific Islander, and other race.

- A high proportion of patients achieved optimal treatment targets at week 16 with upadacitinib treatment **(Table 2)**

Table 2. Achievement of Optimal Treatment Targets at Week 16

Patients, n/n (%) [95% CI]	UPA 15 mg	UPA 30 mg
EASI 90	298/578 (51.6) [47.5, 55.6]	384/572 (67.1) [63.3, 71.0]
WP-NRS 0/1	193/526 (36.7) [32.6, 40.8]	281/529 (53.1) [48.9, 57.4]
Simultaneous EASI 90 + WP-NRS 0/1	156/526 (29.7) [25.8, 33.6]	243/521 (46.6) [42.4, 50.9]

EASI 90, ≥90% improvement from baseline in Eczema Area and Severity Index; UPA, upadacitinib; WP-NRS 0/1, Worst Pruritus Numerical Rating Scale score of 0 or 1 (no/minimal itch) among patients with WP-NRS >1 at baseline.

- The number of patients enrolled in the study decreased over time; among the 448 patients who discontinued the study by week 140, the most common reason for discontinuation was withdrawn consent **(Table 3)**

Table 3. Primary Reasons for Study Discontinuation Through Week 140

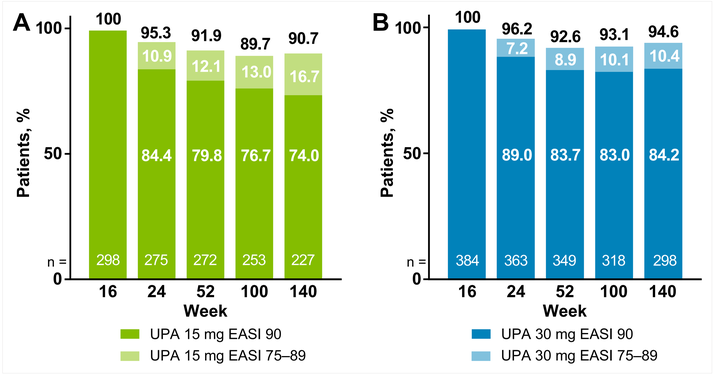
Patients, n (%)	UPA 15 mg (N = 603)	UPA 30 mg (N = 610)
Discontinued study	231 (38.3)	217 (35.6)
Primary reason for study discontinuation		
Withdrawn consent	104 (17.2)	106 (17.4)
Adverse event	33 (5.5)	40 (6.6)
Lost to follow-up	31 (5.1)	20 (3.3)
COVID-19[a]	0	1 (0.2)
Other	63 (10.4)	50 (8.2)

UPA, upadacitinib.
[a]Includes COVID-19 infection and COVID-19 logistical restrictions.

Long-Term Maintenance of Optimal Treatment Targets

- Among patients who achieved EASI 90 at week 16 with upadacitinib 15 mg, 74.0% maintained EASI 90 at week 140; 16.7% did not maintain EASI 90 at week 140 but achieved a clinically meaningful response of EASI 75–89 **(Figure 2A)**
- Among patients who achieved EASI 90 at week 16 with upadacitinib 30 mg, 84.2% maintained EASI 90 at week 140; 10.4% did not maintain EASI 90 at week 140 but achieved a clinically meaningful response of EASI 75–89 **(Figure 2B)**

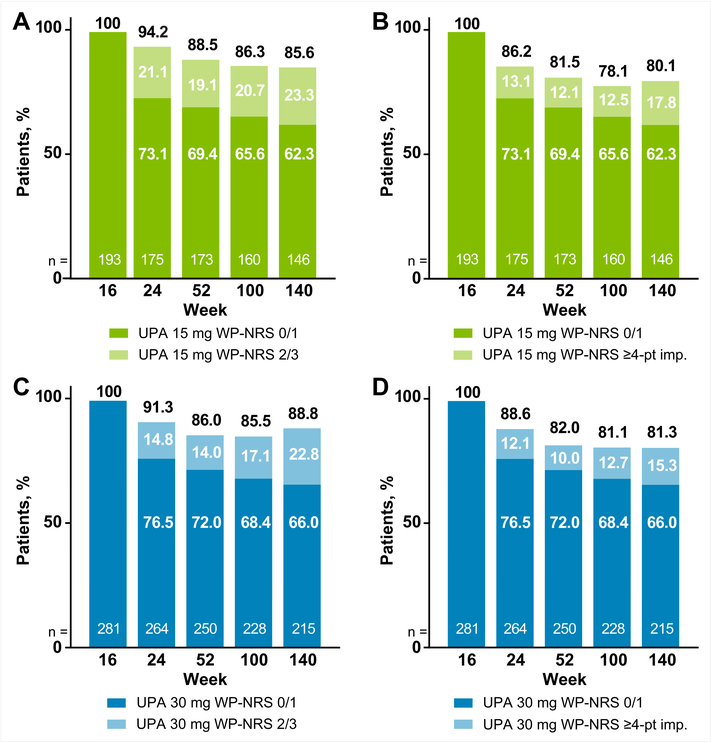
Figure 2. Long-Term Maintenance of EASI 90 With Upadacitinib



EASI 90, ≥90% improvement from baseline in Eczema Area and Severity Index; UPA, upadacitinib.

- Of patients achieving WP-NRS 0/1 at week 16 with upadacitinib 15 mg, 62.3% maintained WP-NRS 0/1 at week 140; 23.3% did not maintain WP-NRS 0/1 at week 140 but reported a score of WP-NRS 2/3 **(Figure 3A)**, and 17.8% achieved a clinically meaningful response of a ≥4-point improvement in WP-NRS at week 140 **(Figure 3B)**
- Of patients achieving WP-NRS 0/1 at week 16 with upadacitinib 30 mg, 66.0% maintained WP-NRS 0/1 at week 140; 22.8% did not maintain WP-NRS 0/1 at week 140 but reported a score of WP-NRS 2/3 **(Figure 3C)**, and 15.3% achieved a clinically meaningful response of a ≥4-point improvement in WP-NRS at week 140 **(Figure 3D)**

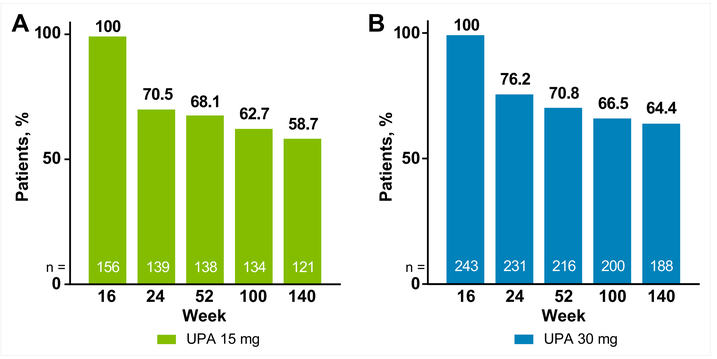
Figure 3. Long-Term Maintenance of WP-NRS 0/1 With Upadacitinib



imp., improvement; pt, point; UPA, upadacitinib; WP-NRS 0/1, Worst Pruritus Numerical Rating Scale score of 0 or 1 (no/minimal itch) among patients with WP-NRS >1 at baseline.

- Of the patients simultaneously achieving EASI 90 + WP-NRS 0/1 responses at week 16, maintenance of these responses was achieved by 58.7% and 64.4% at week 140 with upadacitinib 15 mg and upadacitinib 30 mg, respectively **(Figure 4)**

Figure 4. Long-Term Maintenance of Minimal Disease Activity (Simultaneous EASI 90 + WP-NRS 0/1 Responses) With Upadacitinib



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