Skin Clearance and Itch Relief in Black or African American Patients With Moderate-to-Severe Atopic Dermatitis Treated With Upadacitinib: 140-Week Outcomes From Integrated Phase 3 Measure Up 1 and 2 Studies

Andrew Alexis,[1] Adam Friedman,[2] Nada Elbuluk,[3] Karan Lal,[4,5] Mona Shahriari,[6,7] Chesahna Kindred,[8,9] Chibuzo Obi,[10] Michael Lane,[10] Brian Calimlim,[10] Ayman Grada,[10] Seemal Desai[11,12]

[1]Department of Dermatology, Weill Cornell Medicine, New York, NY, USA; [2]Department of Dermatology, George Washington University School of Medicine and Health Sciences, Washington, DC, USA; [3]Department of Dermatology, University of Southern California, Keck School of Medicine, Los Angeles, CA, USA; [4]Affiliated Dermatology, Scottsdale, AZ, USA; [5]Department of Dermatology, Northwell Health, Glen Cove, NY, USA; [6]Department of Dermatology, Yale University, New Haven, CT, USA; [7]Central Connecticut Dermatology, Cromwell, CT, USA; [8]Kindred Hair and Skin Center, Columbia, MD, USA; [9]Department of Dermatology, Howard University, Washington, DC, USA; [10]AbbVie Inc., North Chicago, IL, USA; [11]Innovative Dermatology, Plano, TX, USA; [12]Department of Dermatology, University of Texas Southwestern Medical Center, Dallas, TX, USA

OBJECTIVE

To assess the efficacy and safety of upadacitinib (UPA) monotherapy at the approved doses of 15 mg and 30 mg once daily in Black or African American patients with moderate-to-severe atopic dermatitis (AD), using an integrated analysis from the Measure Up 1 and Measure Up 2 phase 3 clinical trials

CONCLUSIONS

- Black or African American patients treated daily with oral UPA 15 or 30 mg achieved optimal treatment targets for skin clearance, itch relief, symptom severity, and quality of life, as well as meaningful improvements in sleep
- Most UPA-treated patients who participated in the study achieved substantial improvement in lichenification of upper and lower limbs at week 16
- The short- and long-term safety outcomes were consistent with the known profile for UPA, underscoring its effectiveness for Black or African American patients with moderate-to-severe AD

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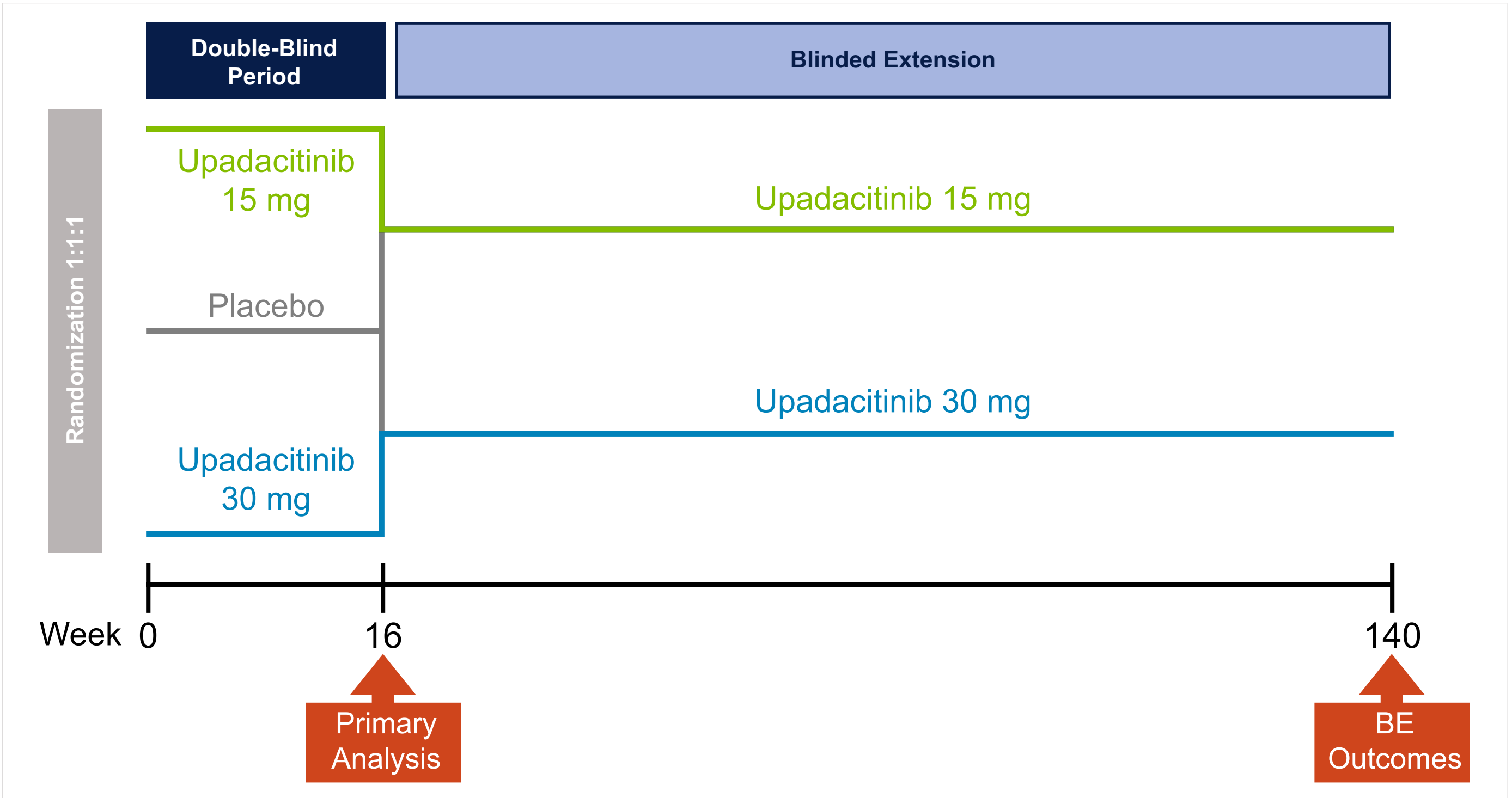
INTRODUCTION

- Clinical phenotypes and molecular endotypes of atopic dermatitis (AD) can vary across different racial groups.[1] Although Black or African American patients have a high burden of lichenification and pruritus,[2] this population is often underrepresented in clinical studies and more evidence is needed to adequately characterize efficacy and safety outcomes for these patients
- Measure Up 1 (NCT03569293) and Measure Up 2 (NCT03607422) were replicate, multicenter, phase 3 clinical trials that evaluated once-daily orally-administered upadacitinib (UPA) monotherapy[3,4]
- This integrated analysis aims to further characterize the efficacy and safety profile of UPA monotherapy at the approved dose of 15 mg or 30 mg once daily in Black or African American patients with moderate-to-severe AD

METHODS

- This post-hoc analysis of Black or African American patients used integrated data from Measure Up 1 and Measure Up 2, where patients were randomized to double-blinded daily oral UPA (15 mg or 30 mg) or placebo for 16 weeks and then completed a long-term blinded extension (BE) period through week 140 with 15 mg or 30 mg daily UPA **(Figure 1)**
- Optimal treatment targets for skin, itch, and quality of life included ≥90% improvement of Eczema Area and Severity Index (EASI 90), validated Investigator Global Assessment for Atopic Dermatitis score of 0 or 1 (vIGA-AD 0/1), Worst Pruritus Numeric Rating Scale of 0 or 1 (WP-NRS 0/1), and Dermatology Life Quality Index of 0 or 1 (DLQI 0/1)
- Achievement of minimal disease activity (MDA), as outlined by Aiming High in Eczema/Atopic Dermatitis (AHEAD) recommendations,[5] was defined as simultaneous achievement of EASI 90 and WP-NRS 0/1
- Improvement in lichenification was assessed using achievement of EASI or Scoring Atopic Dermatitis (SCORAD) component scores of 0 or 1 (None or Mild)
- Clinically meaningful reduction in Patient-Oriented Eczema Measure (ΔPOEM ≥4) and impact of AD on sleep (Atopic Dermatitis Impact Scale Sleep domain; ΔADerm-IS Sleep ≥12) were assessed
- Response rates were based on nonresponder imputation (NRI) during the double-blind period (through week 16) and observed cases (OC) for the BE period (through week 140)
- Adverse events were assessed through week 140

Figure 1. Study Timeline



BE, blinded extension.

RESULTS

Patients

- Baseline demographics for placebo, UPA 15 mg, and UPA 30 mg are listed **(Table 1)**

Efficacy

- At week 16, UPA-treated patients achieved optimal outcomes for skin lesion clearance, itch relief, quality of life, and MDA, as well as clinically meaningful improvement in AD-related sleep disturbance **(Figure 2)**; improvements were sustained through week 140 **(Figure 3)**
- Most patients with moderate-to-severe lichenification at baseline demonstrated substantial improvement in skin lichenification, achieving minimal or no lichenification at week 16 through week 52 **(Figure 4)**

Safety

- Most common adverse events (≥5% of patients) included creatine phosphate elevation, nasopharyngitis, headache, and cough **(Table 2)**
- Adverse events of special interest (AESIs) through weeks 16 and 140 are listed **(Table 3)**
- Long-term safety outcomes are consistent with the known safety profile for UPA, with no new safety signals identified

RESULTS CONTINUED

Table 1. Patient Demographics and Baseline Characteristics

Characteristics	Placebo (n = 37)	UPA 15 mg (n = 43)	UPA 30 mg (n = 26)
Age, years, median (range)	40.0 (12-74)	32.0 (12-73)	34.5 (14-75)
Female, n (%)	23 (62.2)	22 (51.2)	13 (50.0)
Duration since AD symptoms started, years, median (range)	17.6 (3.2-58.3)	21.9 (3.7-59.5)	15.8 (3.8-62.0)
BSA affected, %, median (range)	41.0 (12.0-92.0)	49.5 (16.0-98.0)	32.7 (12.0-95.0)
Clinician-Reported Outcomes			
EASI, median (range)	23.0 (16.0-72.0)	35.0 (17.2-67.2)	22.2 (16.4-69.6)
EASI Upper Limbs Lichenification, n (%)[a]			
Mild	5 (13.5)	3 (7.0)	1 (4.0)
Moderate	15 (40.5)	15 (34.9)	13 (52.0)
Severe	17 (45.9)	25 (58.1)	11 (44.0)
EASI Lower Limbs Lichenification, n (%)			
None	1 (2.7)	1 (2.3)	0 (0.0)
Mild	7 (18.9)	3 (7.0)	2 (8.0)
Moderate	14 (37.8)	11 (25.6)	13 (52.0)
Severe	15 (40.5)	28 (65.1)	10 (40.0)
SCORAD Lichenification, n (%)[a]			
Mild	2 (5.4)	0 (0.0)	1 (4.0)
Moderate	19 (51.4)	17 (39.5)	13 (52.0)
Severe	16 (43.2)	26 (60.5)	11 (44.0)
vIGA-AD, n (%)			
3 (Moderate)	21 (56.8)	15 (34.9)	14 (53.8)
4 (Severe)	16 (43.2)	28 (65.1)	12 (46.2)
Patient-Reported Outcomes			
WP-NRS (Weekly Average), median (range)	7.4 (4.6-10.0)	7.9 (1.9-10.0)	7.0 (4.3-10.0)
DLQI, median (range)	18.0 (8.0-29.0)	14.0 (2.0-29.0)	17.0 (3.0-28.0)
ADerm-IS Sleep, median (range)	20.0 (0.0-30.0)	18.7 (0.3-30.0)	15.7 (3.8-30.0)
POEM, median (range)	22.0 (8.0-28.0)	21.0 (9.0-28.0)	22.0 (10.0-28.0)

ADerm-IS Sleep, atopic dermatitis impact scale sleep; BSA, body surface area; DLQI, dermatology life quality index: EASI, eczema area and severity index; POEM, patient-oriented eczema measure; SCORAD, scoring atopic dermatitis; PUPA, upadacitinib; vIDA-AD, validated investigator global assessment for atopic dermatitis; WP-NRS, worst pruritus numeric rating scale.

[a]No patients met criteria for "None" for this measure.

Table 2. Most Common Adverse Events Through Week 16

Characteristics	Placebo (n = 37)	UPA 15 mg (n = 43)	UPA 30 mg (n = 26)
Blood creatine phosphokinase increased	3 (8.1)	5 (11.6)	2 (7.7)
Nasopharyngitis	1 (2.7)	5 (11.6)	1 (3.8)
Headache	2 (5.4)	5 (11.6)	0
Cough	0	3 (7.0)	1 (3.8)
Acne	0	2 (4.7)	1 (3.8)

UPA, upadacitinib.

Table 3. Treatment-Emergent AESIs Through Week 140

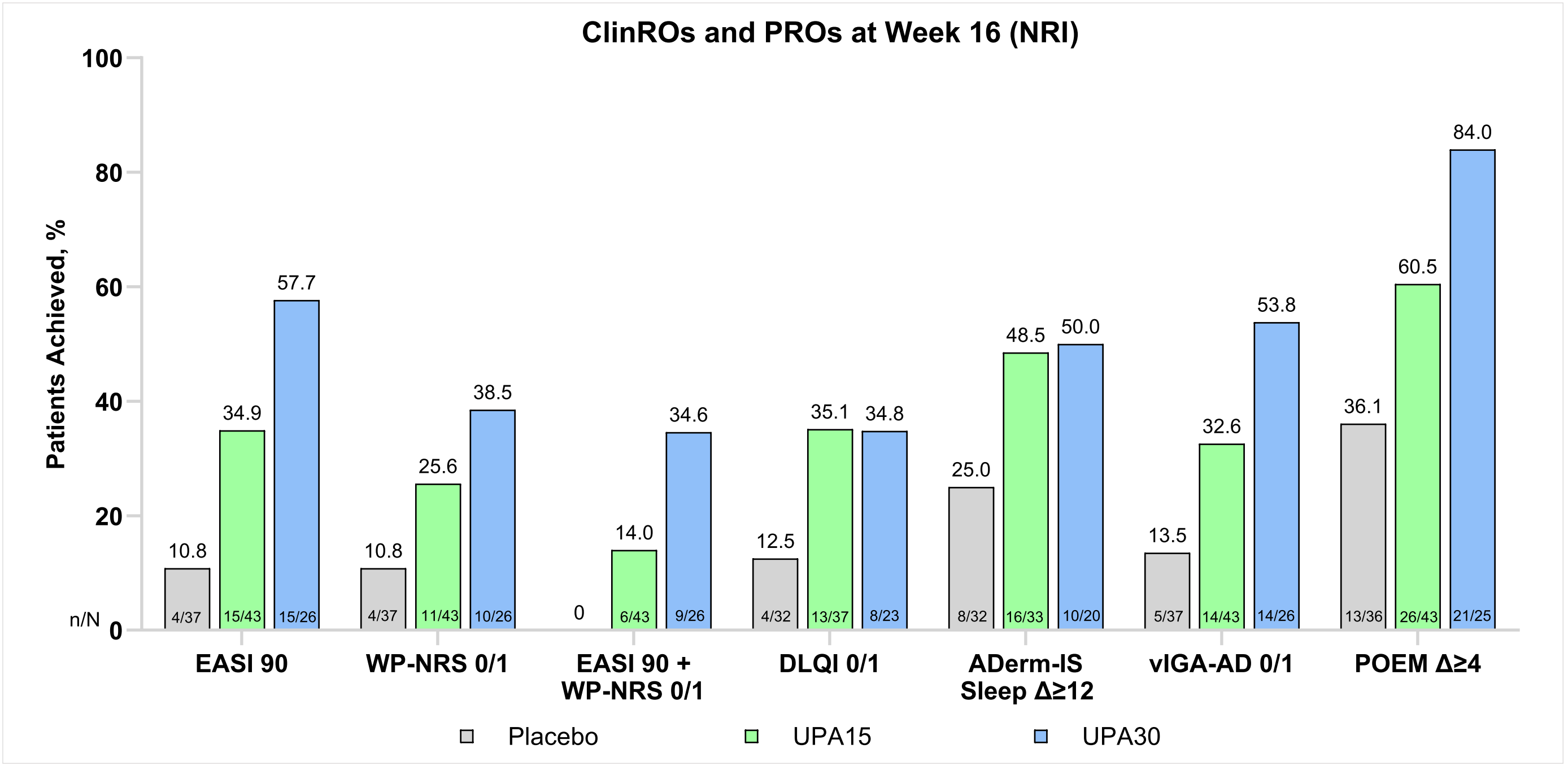
	Double-Blind Period: Week 16			Blinded Extension: Week 140	
AESIs, Exposure Adjusted Rates per 100 PY[a,b]	Placebo (n = 37) PY = 10.4	UPA 15 mg (n = 43) PY = 12.7	UPA 30 mg (n = 26) PY = 7.7	UPA 15 mg (n = 64) PY = 160.2	UPA 30 mg (n = 47) PY = 102.8
Any serious adverse event[a]	9.6	7.9	0	11.2	11.7
Serious infections[a]	0	7.9	0	3.7	2.9
Opportunistic infections[a,c]	0	15.7	0	2.5	1
Herpes zoster[a]	0	0	0	0.6	2.9
Active tuberculosis[a]	0	0	0	0	0
Non-melanoma skin cancer[b]	0	0	0	0	0
Malignancy excluding NMSC[b]	0	0	0	0	0
Lymphoma[b]	0	0	0	0	0
Adjudicated MACE[b]	0	0	0	0.6	0
Adjudicated VTE[b]	0	0	0	0.6	1
Adjudicated gastrointestinal perforation[a]	0	0	0	0	0
Adverse events leading to death[a]	0	0	0	0.6	0

AESIs, Adverse events and serious infections; MACE, major adverse cardiovascular events (defined as cardiovascular death, nonfatal myocardial infarction and nonfatal stroke); NMSC, nonmelanoma skin cancer; PY, patient-years; UPA, upadacitinib; VTE, venous thromboembolic events (defined as deep vein thrombosis and pulmonary embolism [fatal and nonfatal]).

Not all AESIs presented here.

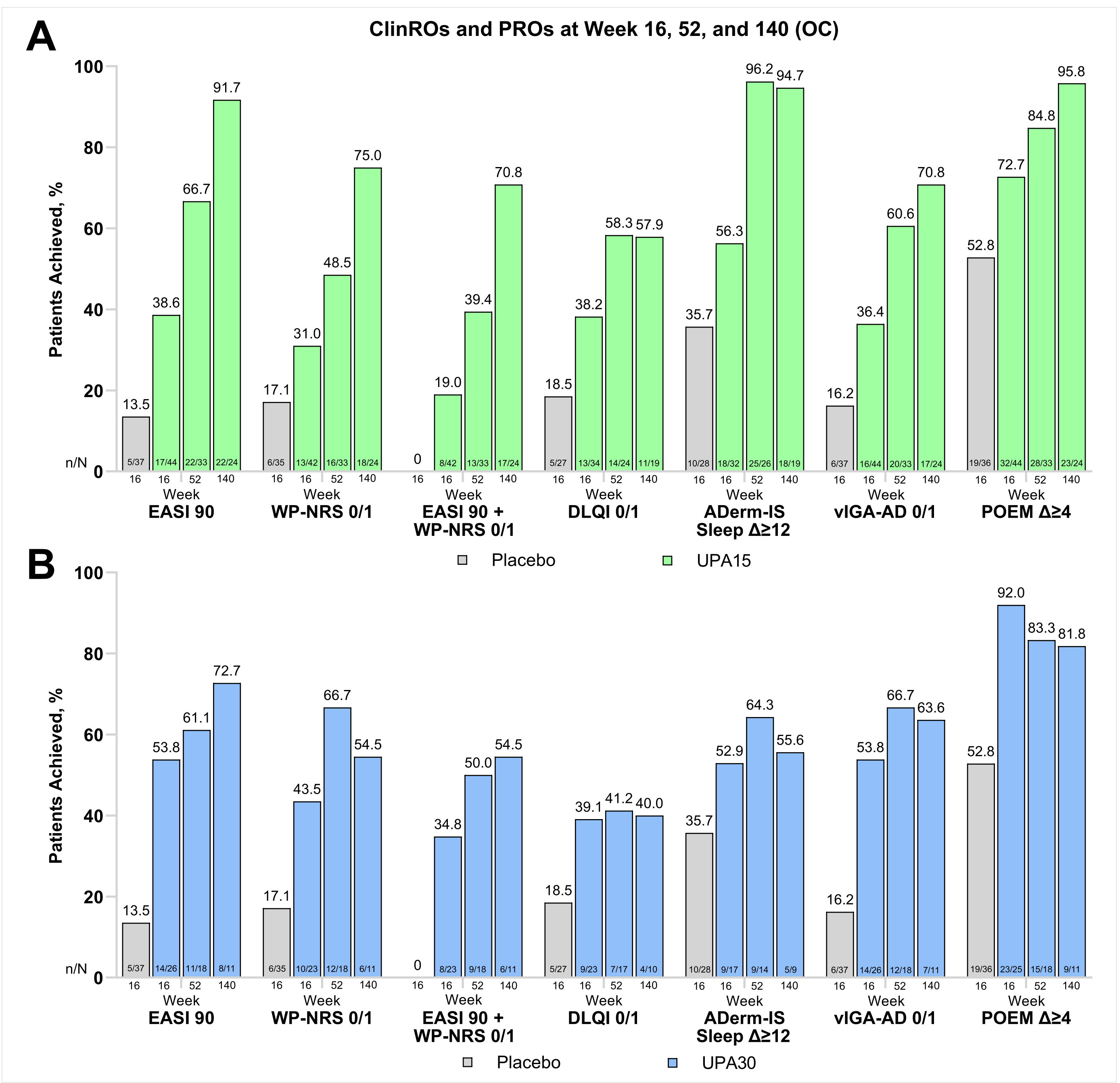
[a]Events per 100 PY; [b]Incidents per 100 PY; [c]Excluding tuberculosis and herpes zoster.

Figure 2. Achievement of Key ClinROs and PROs at Week 16 (NRI)



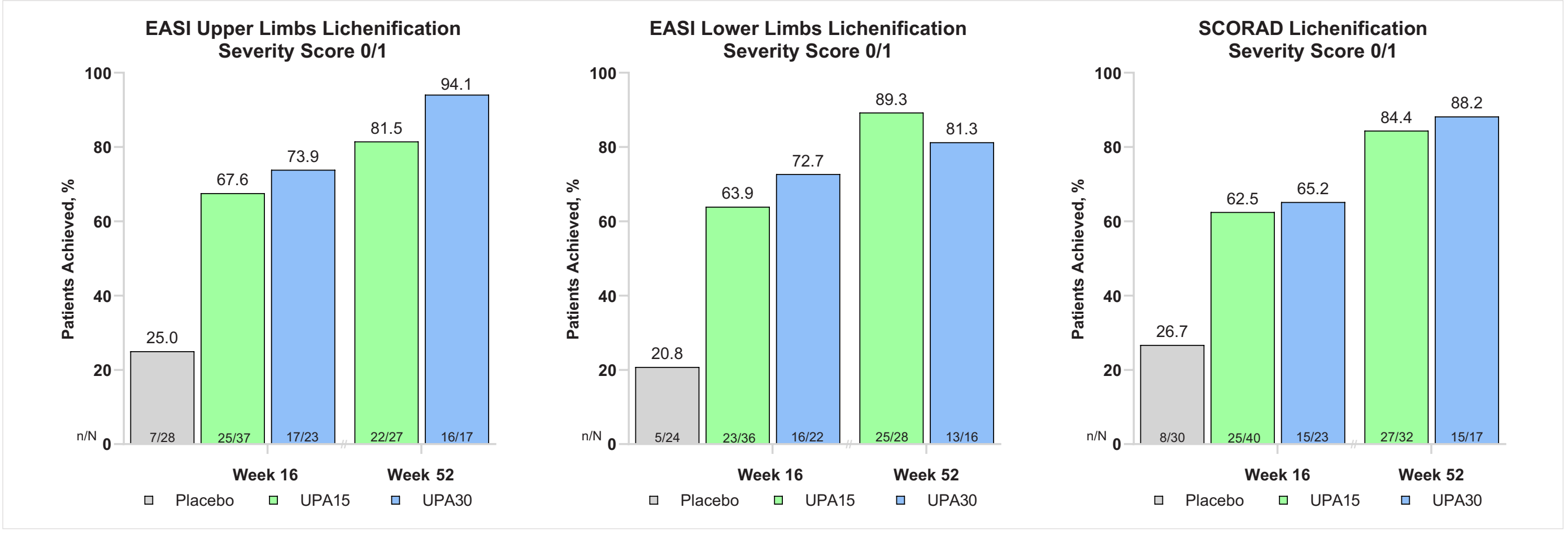
ADerm-IS Sleep, atopic dermatitis impact scale sleep; DLQI, dermatology life quality index; EASI, eczema area and severity index; NRI, nonresponder imputation; POEM, patient-oriented eczema measure; PRO, Patient-reported outcome; UPA, upadacitinib; UPA15, UPA 15 mg; UPA30, UPA 30 mg; vIDA-AD, validated investigator global assessment for atopic dermatitis; WP-NRS, worst pruritus numeric rating scale. Achievement of optimal clinician-reported and patient-reported outcomes for Black or African American patients treated with placebo, UPA 15 mg, or UPA 30 mg presented as NRI data. WP-NRS 0/1 and EASI 90 + WP-NRS 0/1 were evaluated among patients with a WP-NRS score of >1 at Baseline. DLQI 0/1 was evaluated among patients with a score of >1 at Baseline. ADerm-IS Sleep Domain was evaluated among patients with a score of ≥12 at Baseline. vIGA-AD was evaluated among patients with a score of >1 at Baseline. POEM was evaluated among patients with a score of ≥4 at Baseline.

Figure 3. Achievement of Key ClinROs and PROs Through Week 140 (OC)



ADerm-IS Sleep, atopic dermatitis impact scale sleep; DLQI, dermatology life quality index; EASI, eczema area and severity index; OC, observed cases; POEM, patient-oriented eczema measure; PRO, Patient-reported outcome; UPA, upadacitinib; UPA15, UPA 15 mg; UPA30, UPA 30 mg; vIDA-AD, validated investigator global assessment for atopic dermatitis; WP-NRS, worst pruritus numeric rating scale. Achievement of optimal clinician-reported and patient-reported outcomes for Black or African American patients treated with UPA (top) 15 mg or (bottom) 30 mg presented as OC data. WP-NRS 0/1 and EASI 90 + WP-NRS 0/1 were evaluated among patients with a WP-NRS score of >1 at Baseline. DLQI 0/1 was evaluated among patients with a score of >1 at Baseline. ADerm-IS Sleep Domain was evaluated among patients with a score of ≥12 at Baseline. vIGA-AD was evaluated among patients with a score of >1 at Baseline. POEM was evaluated among patients with a score of ≥4 at Baseline.

Figure 4. Reduction in Skin Lichenification



EASI, eczema area and severity index; OC, observed cases; SCORAD, scoring atopic dermatitis; UPA, upadacitinib; UPA15, UPA 15 mg; UPA30, UPA 30 mg.

No-to-mild skin lichenification for (left) upper limbs, (middle) lower limbs, and (right) overall lichenification scores presented as OC data. Skin lichenification was evaluated among patients with baseline scores indicating moderate-to-severe lichenification (EASI or SCORAD Lichenification Severity Score of 2 or 3).

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