Efficacy, Safety, and Tolerability of Upadacitinib in Adults and Adolescents With Severe Alopecia Areata: Results From the Randomized, Placebo-Controlled, Double-Blind Phase 3 Program (UP-AA)

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OBJECTIVE

To assess the efficacy, safety, and tolerability of upadacitinib (UPA) 15 mg once daily (QD) and 30 mg QD compared with placebo for the treatment of signs and symptoms of severe alopecia areata (AA) in adult and adolescent patients

CONCLUSIONS

In 24-week, placebo-controlled period (Period A) of Study 1 and Study 2 of the phase 3 UP-AA program, both UPA 15 mg and UPA 30 mg demonstrated superior and high degrees of efficacy in adults and adolescents with severe AA, compared with placebo

The safety profile of both doses of UPA in Period A was generally consistent with that observed in approved indications

The efficacy, safety, and tolerability of UPA in adult and adolescent patients with severe AA will be further evaluated in the ongoing UP-AA phase 3 clinical program

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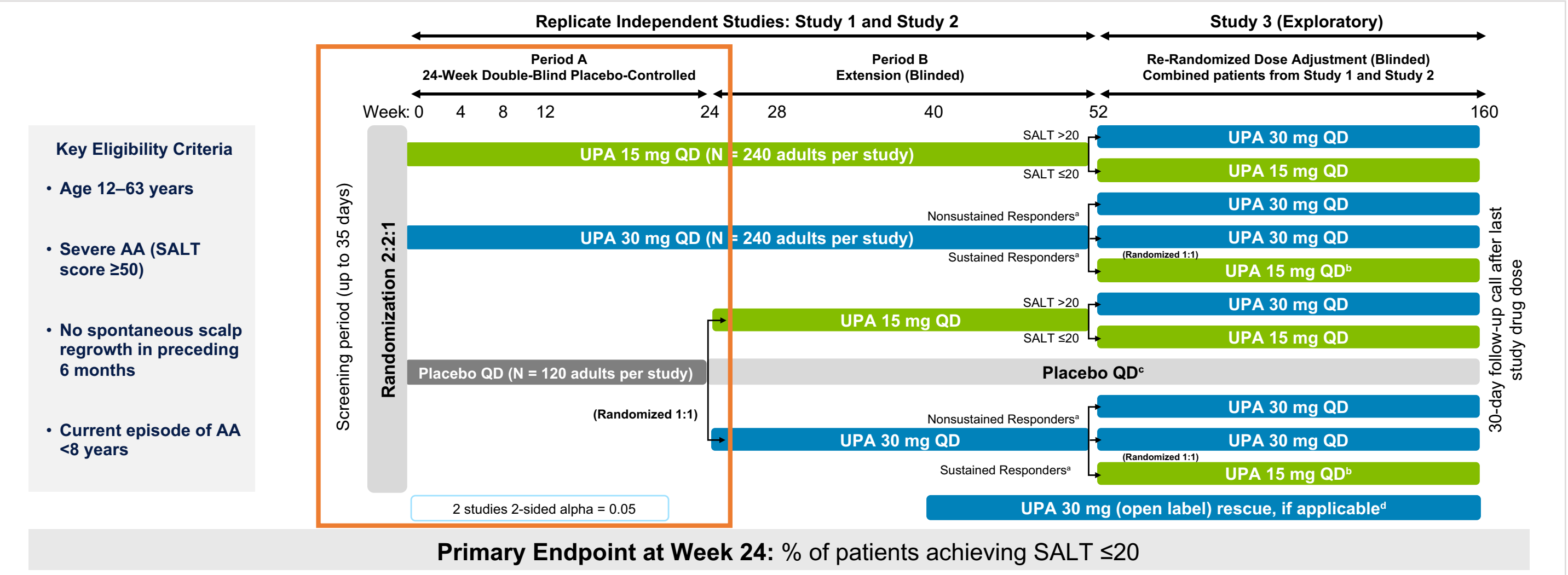
INTRODUCTION

- Alopecia areata (AA) is a complex, systemic immune-mediated disease, characterized by nonscarring hair loss ranging from isolated scalp patches to complete scalp and body hair loss
- Upadacitinib (UPA) is an oral selective Janus kinase inhibitor that is approved for the treatment of several immune-related diseases
- Here, we report the efficacy and safety of UPA vs placebo (PBO) assessed at week 24 primary analysis in the ongoing phase 3, randomized, double-blinded program (UP-AA; NCT06012240) investigating UPA for the treatment of severe AA in adults and adolescents

METHODS

- Patients aged 12–63 years with severe AA (defined as a Severity of Alopecia Tool [SALT] score ≥50) were randomized 2:2:1 to UPA 15 mg, UPA 30 mg, or PBO once daily (QD) for 24 weeks (Period A) in 2 parallel replicate studies (Study 1 and Study 2)
- The primary endpoint of the studies was the achievement of SALT score ≤20 at week 24
- Multiple secondary efficacy endpoints related to improvements in measures of extent of hair loss and health-related quality of life were also assessed through week 24
- Safety was assessed by monitoring adverse events (AEs), laboratory tests, and vital signs

Figure 1. UP-AA Study Design


Replicate Independent Studies: Study 1 and Study 2
Study 3 (Exploratory)
Period A
24-Week Double-Blind Placebo-Controlled
Period B
Extension (Blinded)
Re-Randomized Dose Adjustment (Blinded)
Combined patients from Study 1 and Study 2
Week: 0 4 8 12 24 28 40 52 160
Key Eligibility Criteria
• Age 12–63 years
• Severe AA (SALT score ≥50)
• No spontaneous scalp regrowth in preceding 6 months
• Current episode of AA <8 years
Screening period (up to 35 days)
Randomization 2:2:1
UPA 15 mg QD (N = 240 adults per study)
UPA 30 mg QD (N = 240 adults per study)
Placebo QD (N = 120 adults per study)
(Randomized 1:1)
UPA 15 mg QD
UPA 30 mg QD
SALT >20
SALT ≤20
Nonsustained Responders^a
Sustained Responders^a
(Randomized 1:1)
UPA 30 mg QD
UPA 15 mg QD
UPA 15 mg QD^b
Placebo QD^c
UPA 30 mg (open label) rescue, if applicable^d
2 studies 2-sided alpha = 0.05
30-day follow-up call after last study drug dose
Primary Endpoint at Week 24: % of patients achieving SALT ≤20

AA, alopecia areata; PBO, placebo; QD, once daily; SALT, Severity of Alopecia Tool; UPA, upadacitinib.
[a]Sustained responders are defined as patients with a SALT score ≤20 at week 40 and week 52. Nonsustained responders are defined as patients with a SALT score >20 at week 40 or week 52.
[b]Patients who lose response when re-randomized to UPA 15 mg QD will be re-escalated to UPA 30 mg QD. Loss of response is defined as increase of ≥10 points in absolute SALT score after week 52 re-randomization.
[c]Only for patients receiving PBO with a SALT score ≤20 at week 24 who will remain on PBO until they meet rescue criteria.
[d]Patients with <30% improvement from baseline in their SALT score at the week 40 visit or any scheduled visit thereafter will receive open-label UPA 30 mg QD.

RESULTS

- A total of 1399 patients (Study 1, n = 676; Study 2, n = 723) enrolled in UP-AA and over 91% of patients across all treatment groups completed study medication in Period A **(Figure 2)**
- Demographics and baseline characteristics were well balanced, with mean [SD] SALT scores (83.9 [18.9]) and mean [SD] episode duration in years (3.1 [2.2]) at baseline across all groups **(Table 1)**

Figure 2. Patient Disposition

	Study 1			Study 2		
Randomized	N = 676			N = 723		
Allocated	UPA 15 mg n = 270	UPA 30 mg n = 271	Placebo n = 135	UPA 15 mg n = 289	UPA 30 mg n = 289	Placebo n = 145
Received at least 1 dose of study medication, n (%)	270 (100)	271 (100)	135 (100)	287 (99.3)	289 (100)	145 (100)
Completed study medication in Period A, n (%)	259 (95.9)	254 (93.7)	124 (91.9)	271 (93.8)	270 (93.4)	142 (97.9)
Discontinued study medication, n (%)	11 (4.1)	17 (6.3)	11 (8.1)	16 (5.5)	19 (6.6)	3 (2.1)
Primary Reason: Adverse event, n (%)	2 (0.7)	2 (0.7)	0	2 (0.7)	2 (0.7)	0
Primary Reason: Lost to follow-up, n (%)	4 (1.5)	2 (0.7)	2 (1.5)	3 (1.0)	4 (1.4)	1 (0.7)
Primary Reason: Lack of efficacy, n (%)	0	0	0	0	0	0
Primary Reason: Withdrawal of treatment by patient, n (%)	5 (1.9)	9 (3.3)	8 (5.9)	8 (2.8)	11 (3.8)	2 (1.4)
Primary Reason: Other, n (%)	0	4 (1.5)	1 (0.7)	3 (1.0)	2 (0.7)	0

UPA, upadacitinib.

Table 1. Demographics and Baseline Characteristics

	Study 1			Study 2		
Demographics and characteristics	**UPA 15 mg (N = 270)**	**UPA 30 mg (N = 271)**	**Placebo (N = 135)**	**UPA 15 mg (N = 289)**	**UPA 30 mg (N = 289)**	**Placebo (N = 145)**
Female, n (%)	156 (57.8)	156 (57.6)	79 (58.5)	174 (60.2)	180 (62.3)	81 (55.9)
Age, years, mean (SD)	34.9 (13.7)	35.1 (13.1)	34.6 (12.2)	37.5 (13.6)	36.0 (12.9)	37.2 (14.0)
Adolescent, n (%)	25 (9.3)	26 (9.6)	13 (9.6)	23 (8.0)	21 (7.3)	10 (6.9)
BMI (kg/m²), mean (SD)	25.8 (5.3)	26.1 (6.0)	25.6 (5.4)	26.5 (5.8)	25.3 (5.0)	25.9 (4.9)
AA duration since onset, years, mean (SD)	11.6 (12.1)	10.9 (11.0)	12.7 (11.1)	11.6 (11.4)	12.4 (11.4)	9.9 (9.3)
AA current episode duration, years, mean (SD)	3.1 (2.3)	3.0 (2.2)	3.0 (2.2)	3.0 (2.2)	3.1 (2.3)	3.2 (2.2)
AA current episode ≥3 years, n (%)	115 (42.6)	113 (41.7)	58 (43.0)	126 (43.6)	126 (43.6)	67 (46.2)
SALT score, mean (SD)	84.0 (18.8)	83.8 (18.9)	84.4 (18.1)	84.7 (18.7)	83.6 (19.2)	82.3 (20.0)
SALT score ≥95, n (%)	132 (48.9)	136 (50.2)	65 (48.1)	153 (52.9)	155 (53.6)	75 (51.7)
Alopecia totalis or universalis, n (%)	89 (33.0)	98 (36.2)	52 (38.5)	102 (35.3)	100 (34.6)	54 (37.2)
Alopecia universalis, n (%)	71 (26.3)	71 (26.2)	35 (25.9)	79 (27.3)	85 (29.4)	40 (27.6)
ClinRO eyebrow hair loss severity ≥2, n (%)	170 (63.0)	178 (65.7)	87 (64.4)	192 (66.4)	197 (68.2)	93 (64.1)
ClinRO eyelash hair loss severity ≥2, n (%)	151 (55.9)	145 (53.7)	72 (53.3)	166 (57.4)	158 (54.9)	82 (56.6)

AA, alopecia areata; BMI, body mass index; ClinRO, clinician-reported outcome; SALT, Severity of Alopecia Tool; SD, standard deviation; UPA, upadacitinib.

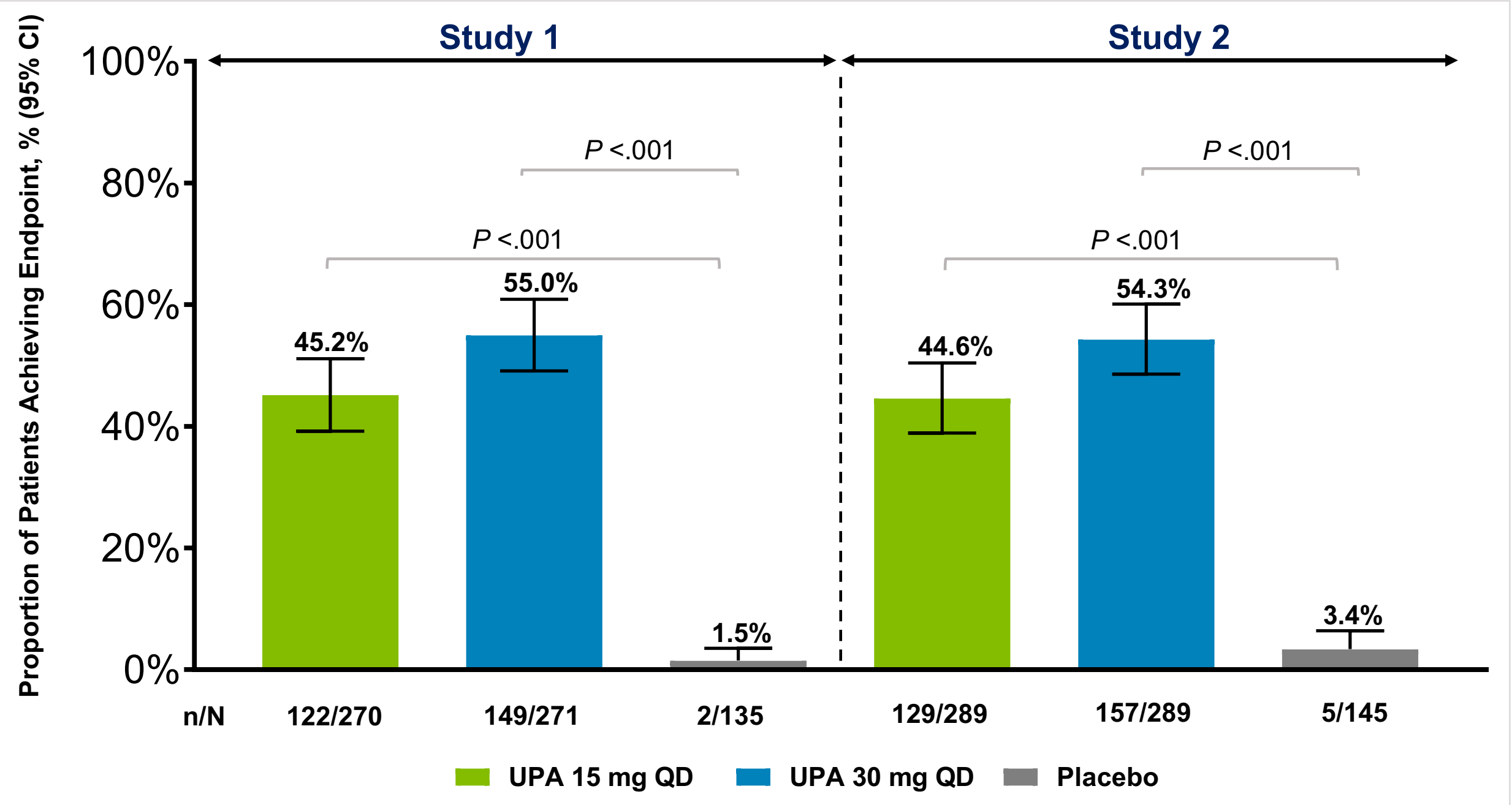
Table 2. Selected Additional Efficacy Endpoints

	Study 1			Study 2		
Selected Secondary Endpoints[a]	**UPA 15 mg (N = 270)**	**UPA 30 mg (N = 271)**	**Placebo (N = 135)**	**UPA 15 mg (N = 289)**	**UPA 30 mg (N = 289)**	**Placebo (N = 145)**
SALT score ≤20, n (%) at Week 12	54 (20.0)*	76 (28.0)*	1 (0.7)	61 (21.1)*	88 (30.4)*	3 (2.1)
Change from BL in Skindex-16 AA Emotions Domain scores, LS mean (SE) at Week 24	-30.1 (1.7)*	-36.2 (1.7)*	-14.6 (2.4)	-31.3 (1.6)*	-34.4 (1.6)*	-10.4 (2.3)
Change from BL in Skindex-16 AA Functioning Domain scores, LS mean (SE) at Week 24	-21.5 (1.5)*	-24.6 (1.5)*	-9.3 (2.2)	-22.5 (1.4)*	-23.4 (1.4)*	-7.0 (2.0)
SALT score ≤20, n (%) at Week 8	19 (7.0)	31 (11.4)*	2 (1.5)	25 (8.7)*	35 (12.1)*	3 (2.1)

AA, alopecia areata; ANCOVA, analysis of covariance; BL, baseline; LS, least square; NRI, nonresponder imputation; RTB-MI, return-to-baseline incorporating multiple imputation; SALT, Severity of Alopecia Tool; SE, standard error; UPA, upadacitinib.
*P <.001 for UPA vs PBO. All P values were statistically significant at the pre-specified 2-sided 0.05 level with multiplicity adjustment. P values were calculated according to the Cochran-Mantel-Haenszel test adjusted for strata based on NRI approach for binary endpoints, and ANCOVA model based on RTB-MI approach for continuous endpoints.
SALT score ≤20 is defined as less than or equal to 20% scalp hair loss; SALT score ≤10 is defined as less than or equal to 10% scalp hair loss; SALT score 0 is defined as 0% scalp hair loss.
[a]The list of secondary endpoints is not comprehensive. The complete list will be included in a future peer reviewed publication.

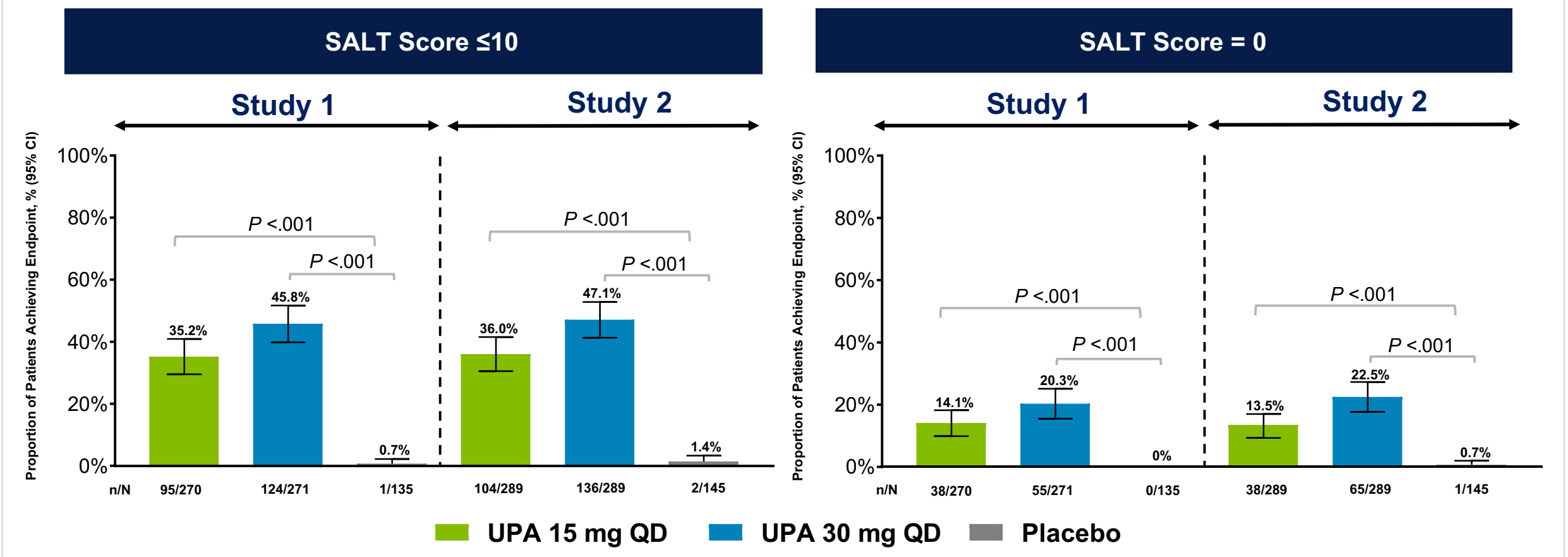
- Both doses of UPA achieved the primary endpoint in both studies — in Period A of Study 1 and Study 2, 44.6–45.2% of patients on UPA 15 mg and 54.3–55.0% on UPA 30 mg achieved 80% or greater scalp hair coverage (SALT ≤20) at week 24, compared with 1.5–3.4% in the PBO group (*P* <.001; **Figure 3**)
- In Study 1, 35.2% and 45.8% of patients treated with UPA 15 mg and 30 mg, respectively, reached 90% or more scalp hair coverage (SALT ≤10), compared with 0.7% of patients receiving PBO at week 24 (*P* <.001; **Figure 4**); in Study 2, 36.0% and 47.1% of patients treated with UPA 15 mg and 30 mg, respectively, achieved SALT ≤10, compared with 1.4% of patients receiving PBO at week 24 (*P* <.001; **Figure 4**)
- Additional key secondary endpoints that were met at week 24 with both doses of UPA included the percentage of patients with improvements in eyebrows and eyelashes **(Figure 5)**, percentage of patients with complete scalp hair coverage (SALT = 0; **Figure 4**), and improvement in multiple domains of health-related quality of life

Figure 3. SALT Score ≤20 at Week 24 (Primary Endpoint; NRI)



NRI, nonresponder imputation; QD, once daily; SALT, Severity of Alopecia Tool; UPA, upadacitinib.
All *P* values were statistically significant at the prespecified 2-sided .05 level with multiplicity adjustment. *P* values were calculated according to the Cochran-Mantel-Haenszel test adjusted for strata based on NRI approach.
SALT score ≤20 is defined as less than or equal to 20% scalp hair loss.

Figure 4. Additional SALT-Based Endpoints at Week 24 (NRI)



NRI, nonresponder imputation; QD, once daily; SALT, Severity of Alopecia Tool; UPA, upadacitinib.
All *P* values were statistically significant at the pre-specified 2-sided .05 level with multiplicity adjustment. *P* values were calculated according to the Cochran-Mantel-Haenszel test adjusted for strata based on NRI approach.
SALT score of ≤10 indicates 10% or less scalp hair loss.
SALT score of 0 indicates no scalp hair loss.

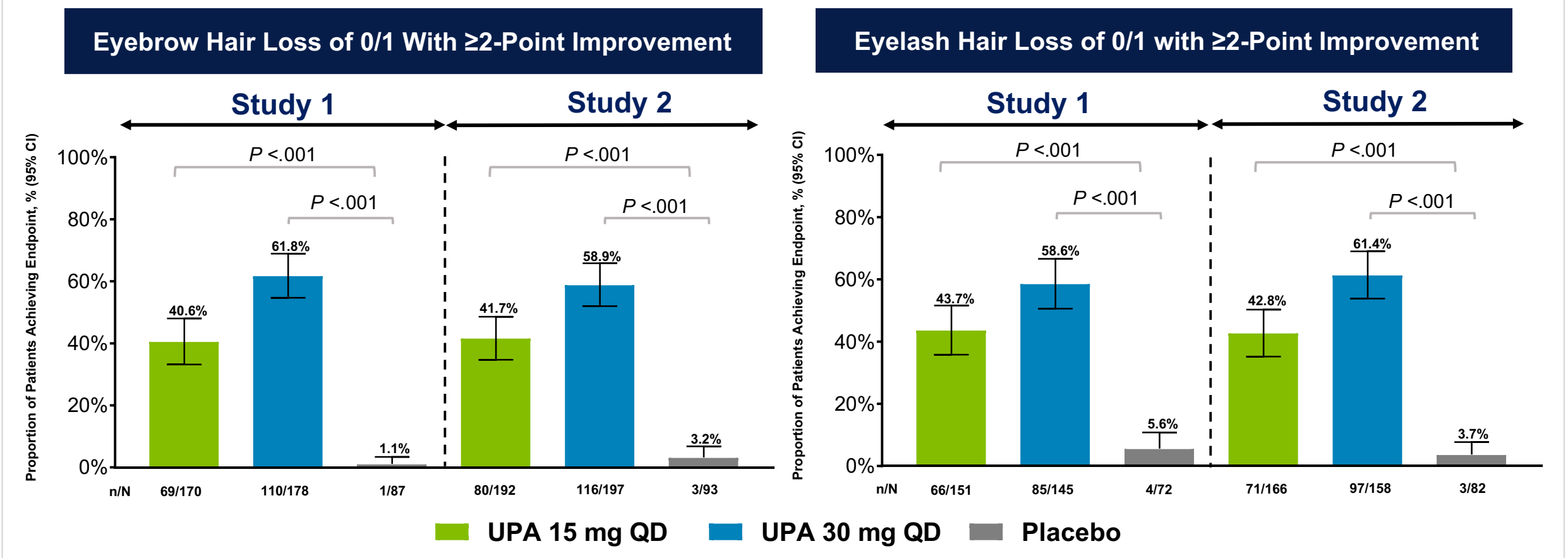
- In both studies, the safety profile of both doses of UPA in Period A was generally consistent with that observed in approved indications
- The most common treatment-emergent adverse events (TEAEs) (>5%) observed were upper respiratory tract infection, acne, increase in blood creatine phosphokinase, and nasopharyngitis **(Table 3)**
- Serious infections were reported infrequently, in 0.4% of the UPA 30 mg group, 0.7% of the placebo group, and none in the UPA 15 mg group of Study 1; 0.7% in the UPA 15 mg group, 1.0% in the UPA 30 mg group, and none in the PBO group of Study 2
- There were no adjudicated major adverse cardiovascular event (MACE), adjudicated gastrointestinal perforations, active tuberculosis, or deaths reported in either study
- One malignancy (breast cancer) was reported in the UPA 15 mg group in Study 1
- One adjudicated venous thromboembolism was reported in the UPA 15 mg group in a patient with multiple risk factors in Study 2

Table 3. Safety

	Study 1			Study 2		
Patients With Any Treatment-Emergent AE, n (%)	**UPA 15 mg (N = 270)**	**UPA 30 mg (N = 271)**	**Placebo (N = 135)**	**UPA 15 mg (N = 289)**	**UPA 30 mg (N = 289)**	**Placebo (N = 145)**
All AEs	161 (59.6)	174 (64.2)	72 (53.3)	188 (65.5)	202 (69.9)	88 (60.7)
Serious AEs	5 (1.9)	5 (1.8)	1 (0.7)	4 (1.4)	8 (2.8)	0
AEs leading to discontinuation of study drug	3 (1.1)	4 (1.5)	0	2 (0.7)	4 (1.4)	0
Deaths	0	0	0	0	0	0
AEs Reported in >5% of Patients, n (%)						
Acne	35 (13.0)	39 (14.4)	2 (1.5)	30 (10.5)	52 (18.0)	8 (5.5)
Nasopharyngitis	29 (10.7)	22 (8.1)	16 (11.9)	38 (13.2)	45 (15.6)	10 (6.9)
Upper respiratory tract infection	26 (9.6)	42 (15.5)	19 (14.1)	27 (9.4)	32 (11.1)	14 (9.7)
Blood creatine phosphokinase increase	20 (7.4)	22 (8.1)	4 (3.0)	9 (3.1)	15 (5.2)	7 (4.8)
Headache	9 (3.3)	11 (4.1)	7 (5.2)	18 (6.3)	12 (4.2)	5 (3.4)

AE, adverse event; UPA, upadacitinib.

Figure 5. ClinRO Endpoints at Week 24 (NRI)



ClinRO, clinician-reported outcome; NRI, nonresponder imputation; QD, once daily; UPA, upadacitinib.
All *P* values were statistically significant at the prespecified 2-sided .05 level with multiplicity adjustment. *P* values were calculated according to the Cochran-Mantel-Haenszel test adjusted for strata based on NRI approach.
The ClinRO for eyebrow hair loss is comprised of the following response options: 0 = The eyebrows have full coverage and no areas of hair loss; 1 = There are minimal gaps in eyebrow hair and distribution is even; 2 = There are significant gaps in eyebrow hair or distribution is not even; 3 = No notable eyebrows.
The ClinRO for eyelash hair loss is comprised of the following response options: 0 = The eyelashes form a continuous line along the eyelids on both eyes; 1 = There are minimal gaps and the eyelashes are evenly spaced along the eyelids on both eyes; 2 = There are significant gaps along the eyelids or the eyelashes are not evenly spaced along the eyelids; 3 = No notable eyelashes.

Table 4. Treatment-Emergent Adverse Events of Special Interest (AESI)

	Study 1			Study 2		
Patients With Any Treatment-Emergent AESI, n (%)	**UPA 15 mg (N = 270)**	**UPA 30 mg (N = 271)**	**Placebo (N = 135)**	**UPA 15 mg (N = 289)**	**UPA 30 mg (N = 289)**	**Placebo (N = 145)**
Serious infections	0	1 (0.4)	1 (0.7)	2 (0.7)	3 (1.0)	0
Opportunistic infection excluding TB and herpes zoster	0	0	0	0	0	0
Active tuberculosis	0	0	0	0	0	0
Herpes zoster	3 (1.1)	2 (0.7)	0	1 (0.3)	4 (1.4)	1 (0.7)
Malignancy	1 (0.4)[a]	0	0	0	0	0
Hepatic disorder	5 (1.9)	14 (5.2)	4 (3.0)	10 (3.5)	4 (1.4)	1 (0.7)
Adjudicated GI perforation	0	0	0	0	0	0
Anemia	3 (1.1)	3 (1.1)	0	1 (0.3)	1 (0.3)	1 (0.7)
Neutropenia	7 (2.6)	11 (4.1)	1 (0.7)	5 (1.7)	11 (3.8)	0
Lymphopenia	1 (0.4)	1 (0.4)	1 (0.7)	0	4 (1.4)	0
Renal dysfunction	0	0	0	0	0	0
Elevated CPK	20 (7.4)	22 (8.1)	4 (3.0)	9 (3.1)	15 (5.2)	7 (4.8)
Adjudicated MACE	0	0	0	0	0	0
Adjudicated VTE	0	0	0	1 (0.3)[b]	0	0
Bone fractures	2 (0.7)	3 (1.1)	0	1 (0.3)	0	1 (0.7)
Retinal detachment	1 (0.4)	0	1 (0.7)	0	0	0
Serious hypersensitivity reactions	0	0	0	0	0	0

CPK, creatine phosphokinase; GI, gastrointestinal; MACE, major adverse cardiovascular event; TB, tuberculosis; UPA, upadacitinib; VTE, venous thromboembolic event.
[a]One malignancy (breast cancer) was reported in the UPA 15 mg group in Study 1.
[b]One patient with multiple risk factors reported VTE on UPA 15 mg in Study 2.

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