

Long-Term Efficacy and Safety of Upadacitinib Through Week 76 in Adults and Adolescents With Non-Segmental Vitiligo: Results From 2 Phase 3 Studies (Viti-Up)

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OBJECTIVE

To assess the long-term efficacy and safety of upadacitinib through 76 weeks of treatment in adults and adolescents with non-segmental vitiligo in two phase 3 studies (Viti-Up)

CONCLUSIONS

Adults and adolescents with non-segmental vitiligo experienced continued improvements in repigmentation outcomes through 76 weeks of upadacitinib treatment

Following crossover from placebo to upadacitinib, patients experienced continued improvements similar to those observed during initial upadacitinib treatment

Upadacitinib was generally well tolerated through week 76; the safety profile remained consistent with previous reports, and exposure-adjusted event rates for TEAEs, severe AEs, and serious AEs were similar to or lower than those reported through week 48

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BACKGROUND

- Non-segmental vitiligo (NSV) is an immune-mediated disease
 - Characterized by unpredictable skin depigmentation
 - With a substantial negative impact on patient quality of life^{1,2}
- Upadacitinib is a selective oral Janus kinase inhibitor
 - Demonstrated clinically meaningful facial and total body repigmentation through week 48 in adults and adolescents with NSV³ in the Viti-Up studies
 - First and only systemic medication approved in the European Union for the treatment of NSV in adults and adolescents aged 12 years and older who are candidates for systemic therapy
- We report the long-term efficacy and safety of upadacitinib through 76 weeks of treatment in the Viti-Up studies, evaluating clinical outcomes with continued upadacitinib treatment and after crossover from placebo

RESULTS

Patients

- Overall, 614 patients were enrolled across Viti-Up-1 (N = 308) and Viti-Up-2 (N = 306), 50% were male and 8.6% were adolescents (aged 12 to <18 years). Mean (SD) baseline T-VASI was 19.4 (12.1) in Viti-Up-1 and 16.8 (10.6) in Viti-Up-2; mean (SD) baseline F-VASI was 1.1 (0.6) in both (Table 1)

Table 1. Baseline Demographics and Disease Characteristics

Characteristic	Viti-Up-1		Viti-Up-2	
	UPA15 N = 206	PBO N = 102	UPA15 N = 205	PBO N = 101
Age, years				
Mean (SD)	44.9 (15.4)	43.6 (14.7)	44.1 (15.3)	45.6 (15.7)
Median (range)	47.0 (12–77)	45.0 (13–69)	46.0 (12–78)	46.0 (12–75)
Sex, n (%)				
Female	108 (52.4)	48 (47.1)	107 (52.2)	44 (43.6)
Male	98 (47.6)	54 (52.9)	98 (47.8)	57 (56.4)
F-VASI, mean (SD)	1.0 (0.6)	1.1 (0.7)	1.1 (0.7)	1.0 (0.6)
T-VASI, mean (SD)	18.7 (11.7)	20.7 (12.9)	16.5 (10.1)	17.5 (11.6)
Baseline disease severity, n (%)				
T-VASI ≤10	57 (27.7)	28 (27.5)	64 (31.2)	33 (32.7)
T-VASI >10	149 (72.3)	74 (72.5)	141 (68.8)	68 (67.3)
Vitiligo disease duration, years, mean (SD)	16.7 (14.8)	16.7 (14.4)	15.7 (12.6)	15.6 (12.0)
VitiQoL total score, mean (SD)	36.2 (26.3)	33.3 (24.2)	38.1 (24.7)	34.4 (24.7)
With prior topical therapy for vitiligo ^a , n (%)	116 (56.3)	54 (52.9)	118 (57.6)	63 (62.4)
With prior phototherapy for vitiligo ^a , n (%)	67 (32.5)	34 (33.3)	67 (32.7)	32 (31.7)

F-VASI, Facial Vitiligo Area Scoring Index; PBO, placebo; T-VASI, Total Vitiligo Area Scoring Index; UPA15, upadacitinib 15 mg; VitiQoL, Vitiligo-Specific Quality of Life.
Prior topical therapy includes topical corticosteroids and topical calcineurin inhibitors.
Prior phototherapy includes phototherapy, photodynamic therapy, and laser (phototherapy equivalent).

Improvements in Repigmentation

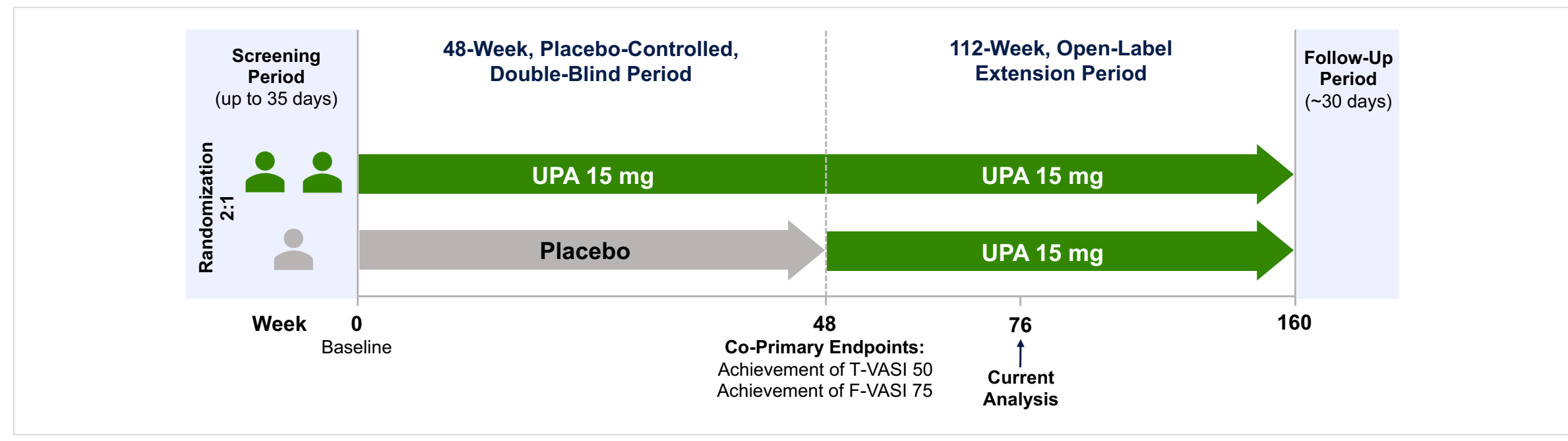
- As reported previously,³ a significantly greater proportion of patients receiving upadacitinib achieved each T-VASI 50 and F-VASI 75 at week 48 compared with patients receiving placebo (Figure 2)
- After week 48, the proportion of patients receiving continuous upadacitinib who achieved each T-VASI 50 and F-VASI 75 continually increased at each visit through week 76
- An increase in the proportion of patients achieving each T-VASI 50 and F-VASI 75 was observed after patients switched from placebo to upadacitinib at week 48
- As reported previously,³ upadacitinib-treated patients achieved significantly greater reductions (improvement) from baseline in each T-VASI and F-VASI compared with patients receiving placebo at week 48 (Figure 3)
- After week 48, patients randomized to upadacitinib achieved continuous improvements (reductions from baseline) in each T-VASI and F-VASI at each visit through week 76 with no observed flattening of the curves
- After switching to upadacitinib at week 48, patients initially randomized to placebo achieved greater improvements (reductions from baseline) in each T-VASI and F-VASI
- At week 76, almost 33% of patients treated with continuous upadacitinib reported their vitiligo as “A lot less noticeable (4)” or “No longer noticeable (5)” (Figure 4)
- An additional 7.5% of patients who crossed over from placebo (n = 107) reported their vitiligo as “A lot less noticeable (4)” or “No longer noticeable (5)” after 28 weeks of upadacitinib treatment

Safety

- Upadacitinib was generally well tolerated through 76 weeks of treatment; TEAEs were consistent with the overall upadacitinib known safety profile (Table 2)
- AESIs were infrequent, with no reported venous thromboembolic events, opportunistic infections, or active tuberculosis; 1 major adverse cardiovascular event (subarachnoid hemorrhage) deemed unrelated to study drug per the investigator was reported in an adult
- Potentially clinically significant (grade ≥3) laboratory findings were infrequent and transient, and none resulted in study drug discontinuation

METHODS

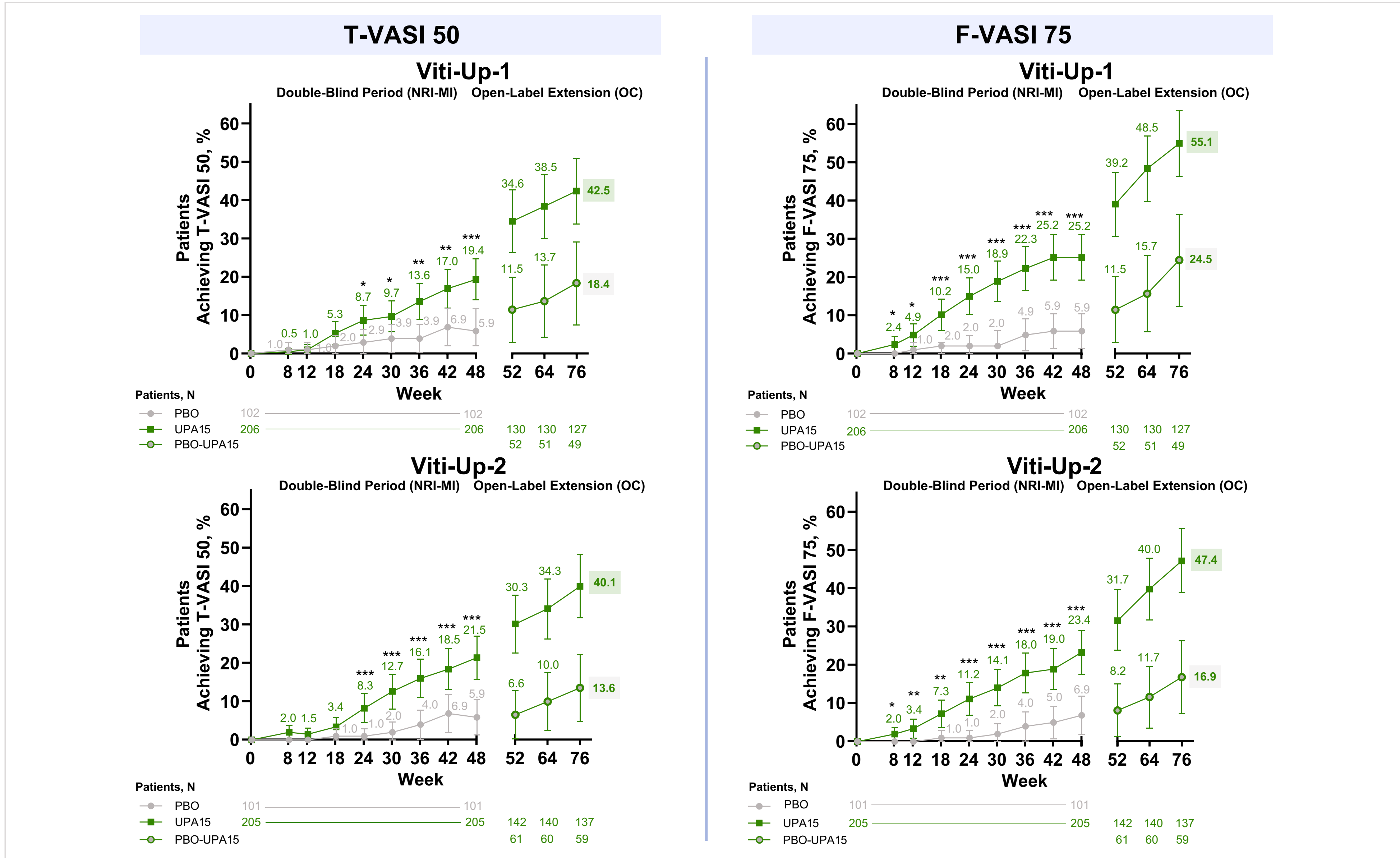
Figure 1. Study Design



F-VASI 75, ≥75% reduction from baseline in Facial Vitiligo Area Scoring Index; T-VASI, Total Vitiligo Area Scoring Index; T-VASI 50, ≥50% reduction from baseline in Total Vitiligo Area Scoring Index; UPA15, upadacitinib 15 mg.

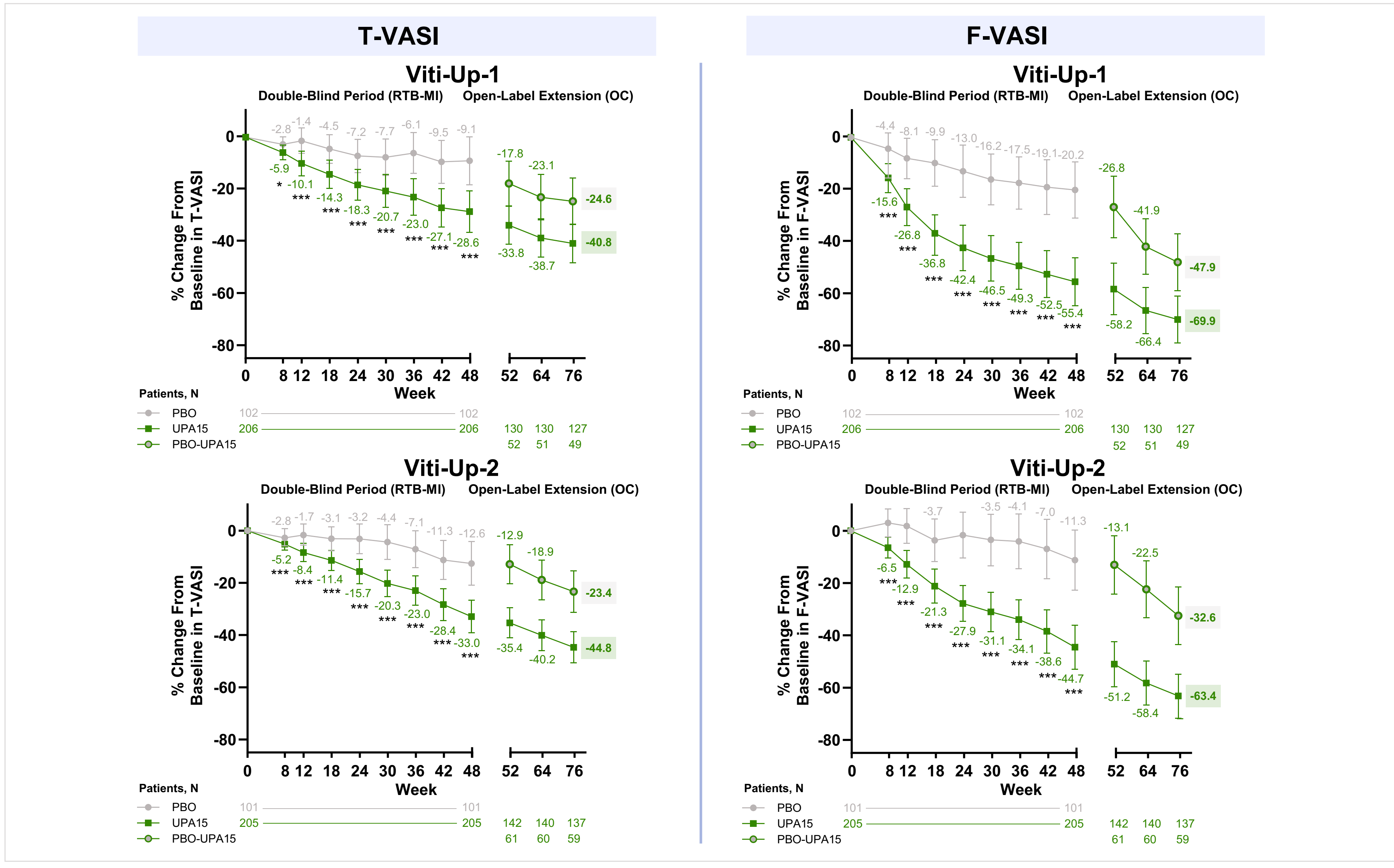
- Viti-Up (NCT06118411) is comprised of 2 replicate phase 3, global, randomized, double-blind, placebo-controlled, multicenter studies (Viti-Up-1; Viti-Up-2) (Figure 1)

Figure 2. Patients Achieving T-VASI 50 and F-VASI 75 Through Week 76 of the Viti-Up Studies



F-VASI, Facial Vitiligo Area Scoring Index; T-VASI 75, ≥75% reduction from baseline in F-VASI; NRI-MI, nonresponder imputation with multiple imputation; OC, observed cases; PBO, placebo; PBO-UPA15, patients who crossed over from placebo to UPA15; T-VASI, Total Vitiligo Area Scoring Index; T-VASI 50, ≥50% reduction from baseline in T-VASI; UPA15, upadacitinib 15 mg.
Analyses through week 48 used nonresponder imputation with multiple imputation for missing-at-random data; efficacy analyses from weeks 52–76 were based on observed cases, with no imputation for missing data.
*P < .05; **P < .01; ***P < .001 vs placebo; Week 24 and week 48 F-VASI 75 responses and week 24 T-VASI 50 responses were prespecified ranked endpoints. P values for all other time points are nominal.

Figure 3. Mean Percent Change From Baseline in T-VASI and F-VASI Through Week 76 of the Viti-Up Studies



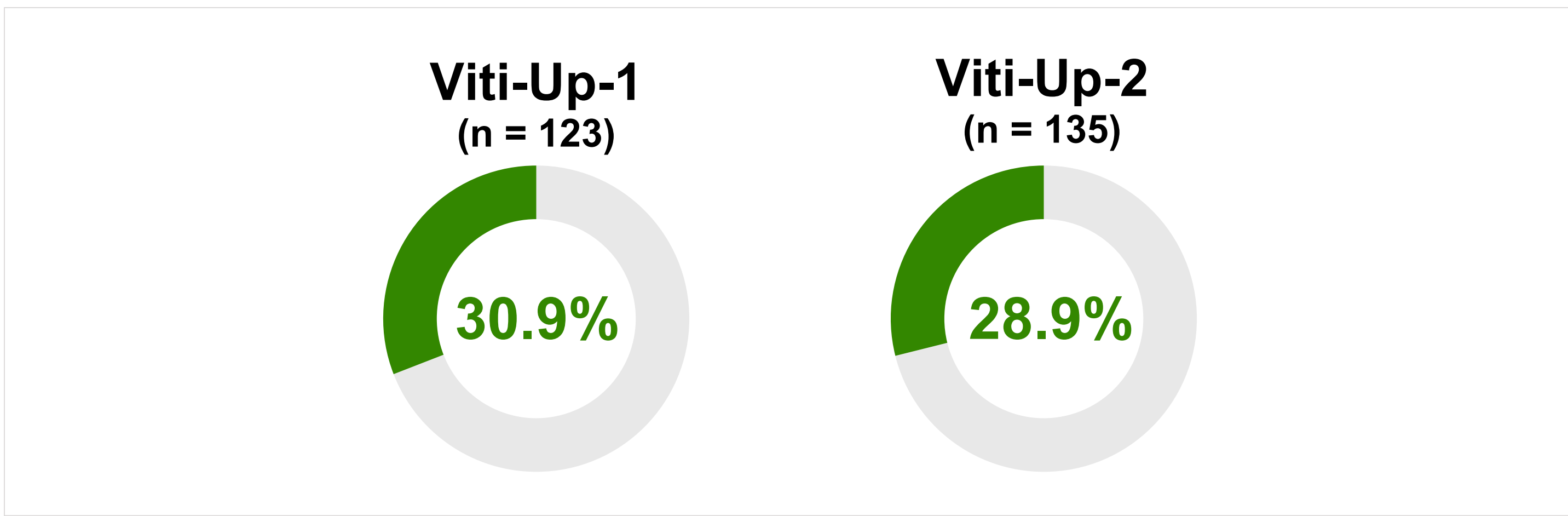
ANCOVA, analysis of covariance; F-VASI, Facial Vitiligo Area Scoring Index; LS, least squares; OC, observed cases; PBO, placebo; PBO-UPA15, patients who crossed over from placebo to UPA15; RTB-MI, multiple imputation incorporating return-to-baseline; T-VASI, Total Vitiligo Area Scoring Index; UPA15, upadacitinib 15 mg.
The LS mean and 95% CI in percent change from baseline analyses were calculated from ANCOVA with baseline value, treatment, and stratification factors as covariates.
Through week 48, multiple imputation was the primary approach for handling missing values; missing data after discontinuation of study treatment due to lack of efficacy were handled by return to baseline; analyses from weeks 52–76 were based on observed cases, with no imputation for missing data.
*P < .05; **P < .01; ***P < .001 vs placebo; Percent change from baseline in F-VASI 75 at week 24 and T-VASI 50 at week 48 were prespecified ranked endpoints. P values for all other time points are nominal.

- Patient-reported outcomes included proportion of patients achieving a Vitiligo Noticeability Scale (VNS) score of “A lot less noticeable (4)” or “No longer noticeable (5)”
- Safety was assessed by monitoring treatment-emergent adverse events (TEAEs), adverse events of special interest (AESIs), and laboratory values

Statistical Analysis

- Efficacy analyses through week 48 used nonresponder imputation while incorporating multiple imputation for missing-at-random data
 - For percent change from baseline analyses, multiple imputation was the primary approach for handling missing values; missing data after discontinuation of study treatment due to lack of efficacy were handled by return to baseline
- Efficacy analyses from weeks 52–76 were based on observed cases, with no imputation for data

Figure 4. Patients Achieving a VNS Score of “A Lot Less Noticeable (4)” or “No Longer Noticeable (5)” at Week 76 of Upadacitinib Treatment



UPA15, upadacitinib 15 mg; VNS, Vitiligo Noticeability Scale.
At week 76, a VNS score of “A lot less noticeable (4)” or “No longer noticeable (5)” was achieved by 8.2% (n = 48) and 6.9% (n = 58) of patients who switched from placebo to UPA15 in Viti-Up-1 and Viti-Up-2, respectively.

Table 2. Overview of TEAEs and AESIs per 100 PY for Patients Receiving Upadacitinib 15 mg During the Viti-Up Studies

	Events/100 PY			
	Viti-Up-1 (N = 276)		Viti-Up-2 (N = 277)	
	Week 48 (PY = 244.2)	Week 76 (PY = 349.5)	Week 48 (PY = 245.9)	Week 76 (PY = 355.6)
TEAEs, n (%)				
Any	588 (240.8)	721 (206.3)	589 (239.6)	766 (215.4)
AE related to study drug ^a	239 (97.9)	301 (86.1)	164 (66.7)	204 (57.4)
Severe AE	22 (9.0)	30 (8.6)	23 (9.4)	28 (7.9)
Serious AE	12 (4.9)	17 (4.9)	10 (4.1)	13 (3.7)
Leading to study drug discontinuation	7 (2.9)	10 (2.9)	8 (3.3)	12 (3.4)
Leading to death	0	0	0	0
AESIs, n (%)				
Serious infections	5 (2.0)	5 (1.4)	0	2 (0.6)
Malignancy excluding NMSC	1 (0.4)	2 (0.6)	0	0
Hepatic disorders	16 (6.6)	20 (5.7)	5 (2.0)	9 (2.5)
Anemia	5 (2.0)	6 (1.7)	4 (1.6)	4 (1.1)
Neutropenia	9 (3.7)	10 (2.9)	7 (2.8)	8 (2.2)
Lymphopenia	3 (1.2)	5 (1.4)	6 (2.4)	7 (2.0)
Bone fracture	6 (2.5)	9 (2.6)	4 (1.6)	6 (1.7)
Herpes zoster	9 (3.7)	10 (2.9)	3 (1.2)	4 (1.1)
Renal dysfunction	0	0	0	1 (0.3)
Adjudicated GI perforations	0	0	0	0
Adjudicated MACE ^{b,c}	0	1 (0.3)	0	0
Adjudicated VTE ^d	0	0	0	0
Active tuberculosis	0	0	0	0
Opportunistic infections ^e	0	0	0	0

AESIs, adverse events of special interest; GI, gastrointestinal; MACE, major adverse cardiovascular event; NMSC, non-melanoma skin cancer; PY, patient-years; TEAE, treatment-emergent adverse event; VTE, venous thromboembolism.
^aAccording to the investigator.
^bDefined as cardiovascular death, nonfatal myocardial infarction, and nonfatal stroke.
^cAdult patient with recurrent migraines who experienced a subarachnoid hemorrhage during physical exercise; a sacular aneurysm was identified as the likely source; deemed unrelated to study drug per the investigator.
^dIncludes deep vein thromboses and pulmonary embolism (fatal and nonfatal).
^eExcluding tuberculosis and herpes zoster.