#6479
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Efficacy of Prolonged Ruxolitinib Cream Treatment for Vitiligo Among Patients With Limited or No Initial Response at 6 Months

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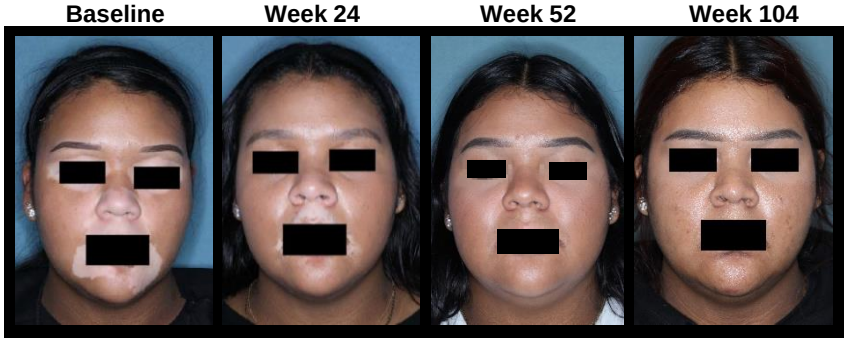
Presenting Author Disclosures

- Dermatologist at the Netherlands Institute for Pigment Disorders and the Department of Dermatology at the Amsterdam University Medical Center
- Principal investigator for Avita Medical, Incyte Corporation, and Novartis
- Advisory board member for Incyte Corporation
- Research support from Avita Medical and Lumenis
- Received devices from Humeca and PerfAction

Ruxolitinib Cream for Vitiligo

- In 2 randomized, double-blind, vehicle-controlled phase 3 studies in adults and adolescents with vitiligo (TRuE-V1/TRuE-V2), ruxolitinib (JAK1/JAK2 inhibitor) cream application resulted in substantial repigmentation and was well tolerated over 52 weeks[1]
  - Further improvements in facial and body repigmentation were observed through Week 104 in the TRuE-V LTE[2]
- **Objective:** To evaluate long-term responses among patients who had no or limited repigmentation response at Week 24

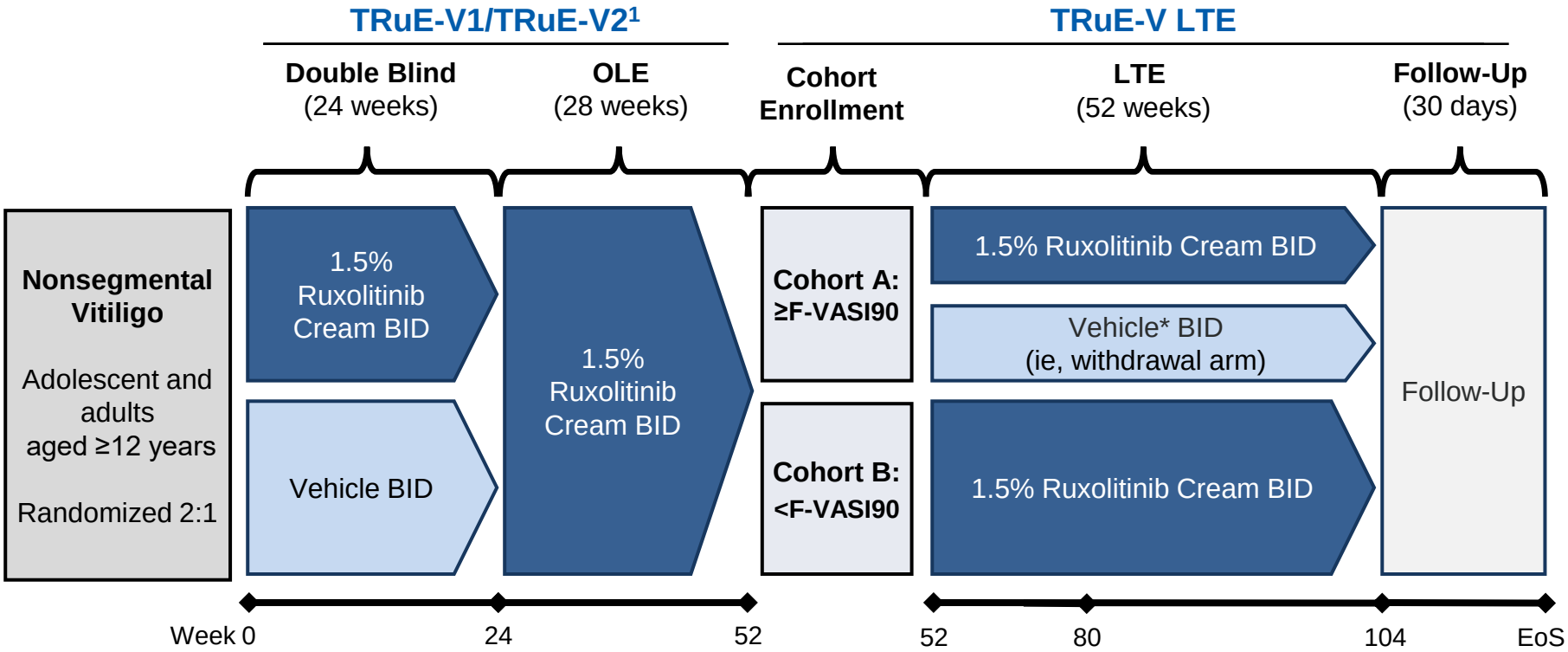
Patient Who Achieved F-VASI90 at Week 52 in the TRuE-V Studies



F-VASI90, 90% improvement in facial Vitiligo Area Scoring Index; JAK, Janus kinase; LTE, long-term extension; TRuE-V, Topical Ruxolitinib Evaluation in Vitiligo trials.

1. Rosmarin D, et al. *N Engl J Med.* 2022;387:1445-1455. 2. Rosmarin D, et al. Facial and total Vitiligo Area Scoring Index response shift during 104 weeks of ruxolitinib cream treatment for vitiligo: results from the open-label arm of the TRuE-V long-term extension phase 3 study. Presented at: American Academy of Dermatology (AAD) Annual Meeting; March 17-23, 2023; New Orleans, LA.

Overview of TRuE-V Studies



BID, twice daily; EoS, end of study; F-VASI75, 75% improvement in facial Vitiligo Area Scoring Index; OLE, open-label extension.
* Patients randomized to vehicle who relapsed (ie, <F-VASI75) could apply 1.5% ruxolitinib cream BID rescue treatment for the remainder of the LTE period.

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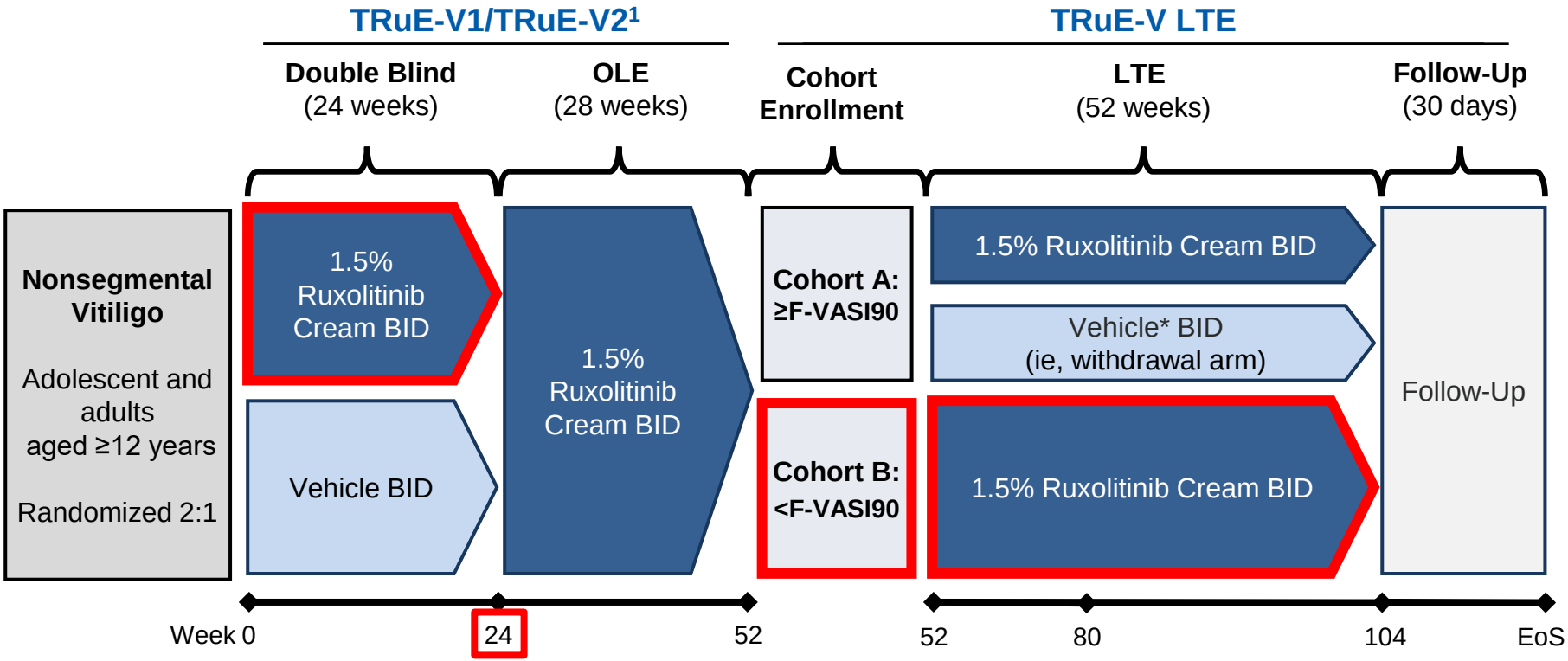
Overview of TRuE-V Studies



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Baseline Patient Demographics

TRuE-V LTE Cohort B (<F-VASI90 at Week 52)

Characteristic	Ruxolitinib Cream From Day 1 (n=224)
Age, median (range), y	39.0 (12–79)
Female, n (%)	129 (57.6)
White, n (%)	180 (80.4)
Fitzpatrick skin type, n (%)	
I	6 (2.7)
II	51 (22.8)
III	106 (47.3)
IV	43 (19.2)
V	13 (5.8)
VI	5 (2.2)
Baseline F-VASI, mean (SD)	0.91 (0.55)
Baseline T-VASI, mean (SD)	6.73 (2.02)

Characteristic	Ruxolitinib Cream From Day 1 (n=224)
F-BSA,* mean (SD), %	1.02 (0.64)
T-BSA, mean (SD), %	7.50 (2.00)
Duration of disease, median (range), y	11.7 (0–54.4)
Diagnosed in childhood, n (%)	86 (38.4)
Disease stability,† n (%)	
Stable	167 (74.6)
Progressive	57 (25.4)
Other autoimmune disorders, n (%)	42 (18.8)
Previous therapy,‡ n (%)	138 (61.6)
Topical calcineurin inhibitor	79 (35.3)
Topical corticosteroid	72 (32.1)
Phototherapy§	70 (31.3)

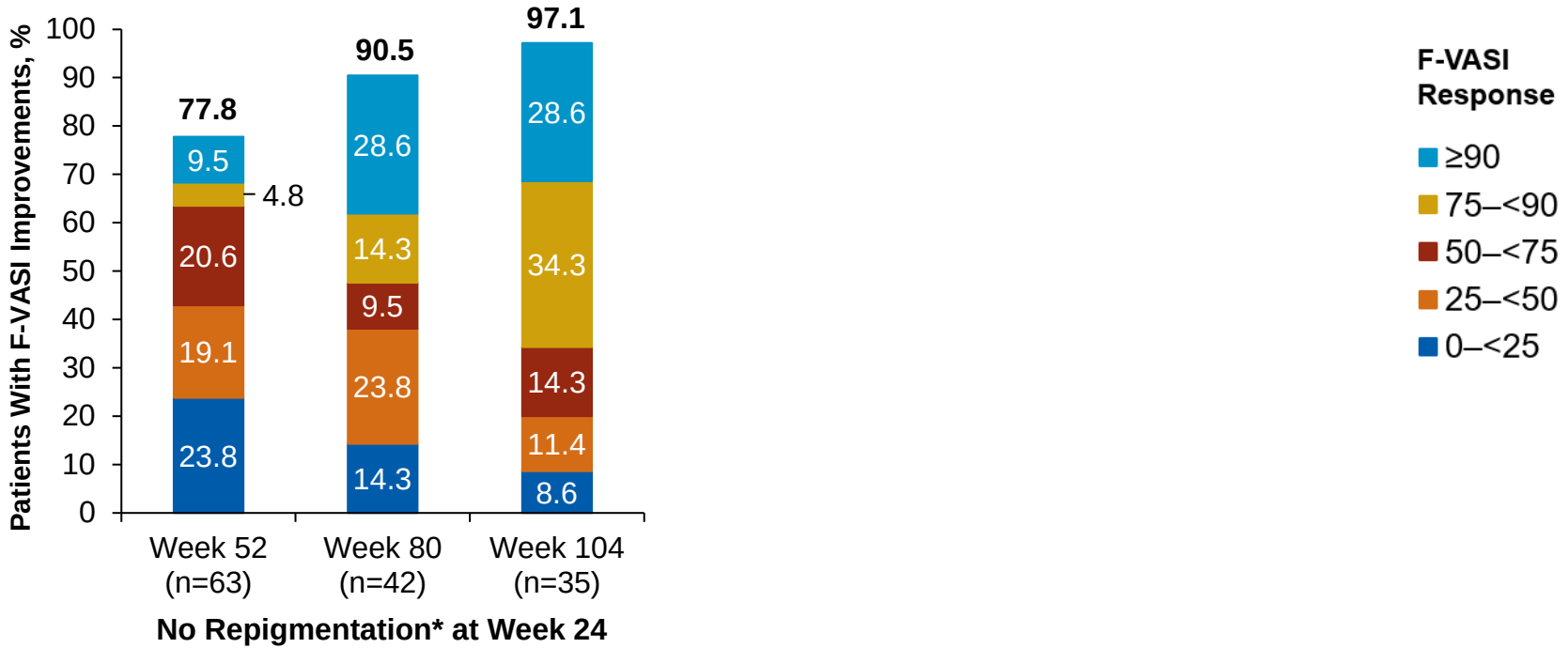
F-BSA, facial body surface area; F-VASI, facial Vitiligo Area Scoring Index; NB-UVB, narrow-band ultraviolet-B; PUVA, psoralen ultraviolet-A; T-BSA, total body surface area; T-VASI, total Vitiligo Area Scoring Index.

* Percentage of T-BSA. † Determination of disease stability was based on investigator judgment. ‡ Patients could have received multiple previous therapies. § Includes excimer laser, NB-UVB phototherapy, PUVA photochemotherapy, and other phototherapy.

F-VASI Response at Weeks 52–104

Patients With No or Limited Facial Repigmentation at Week 24

- 71.7% and 90.1% of patients had F-VASI improvements at Weeks 52 and 104, respectively



***** Patients with worsening or no improvement in F-VASI (ie, ≤0%) at Week 24 and nonmissing F-VASI values at Weeks 52, 80, or 104. Data at Weeks 80 and 104 are from Cohort B.

† Patients with >0%–<25% improvement in F-VASI at Week 24 and nonmissing F-VASI values at Weeks 52, 80, or 104. Data at Weeks 80 and 104 are from Cohort B.

F-VASI Response at Weeks 52–104

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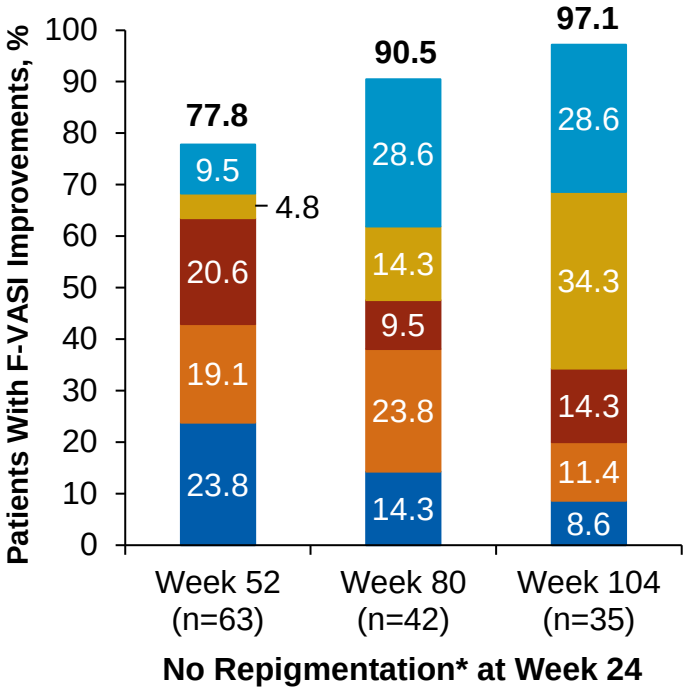
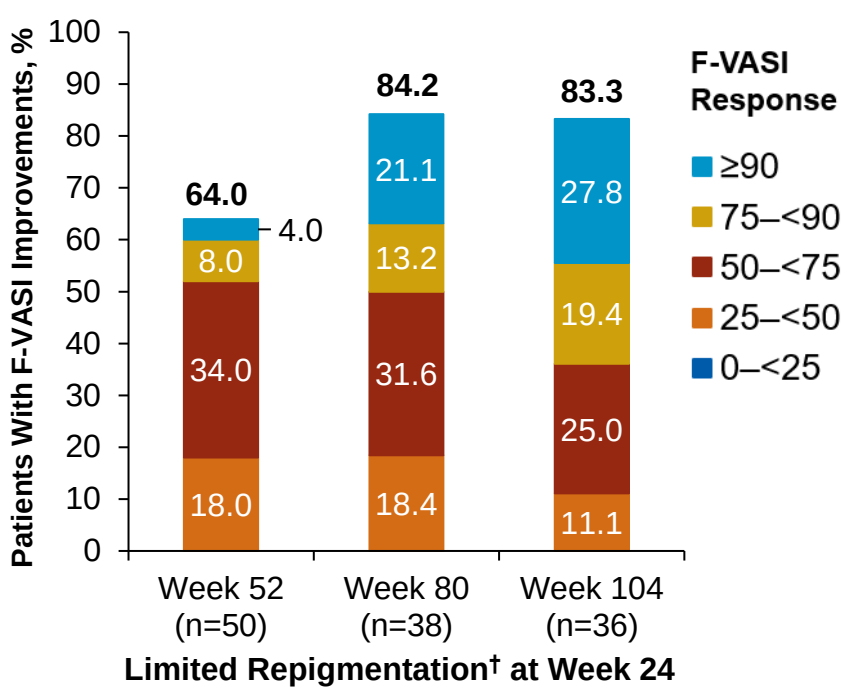


No Repigmentation* at Week 24



Limited Repigmentation† at Week 24

***** Patients with worsening or no improvement in F-VASI (ie, ≤0%) at Week 24 and nonmissing F-VASI values at Weeks 52, 80, or 104. Data at Weeks 80 and 104 are from Cohort B.

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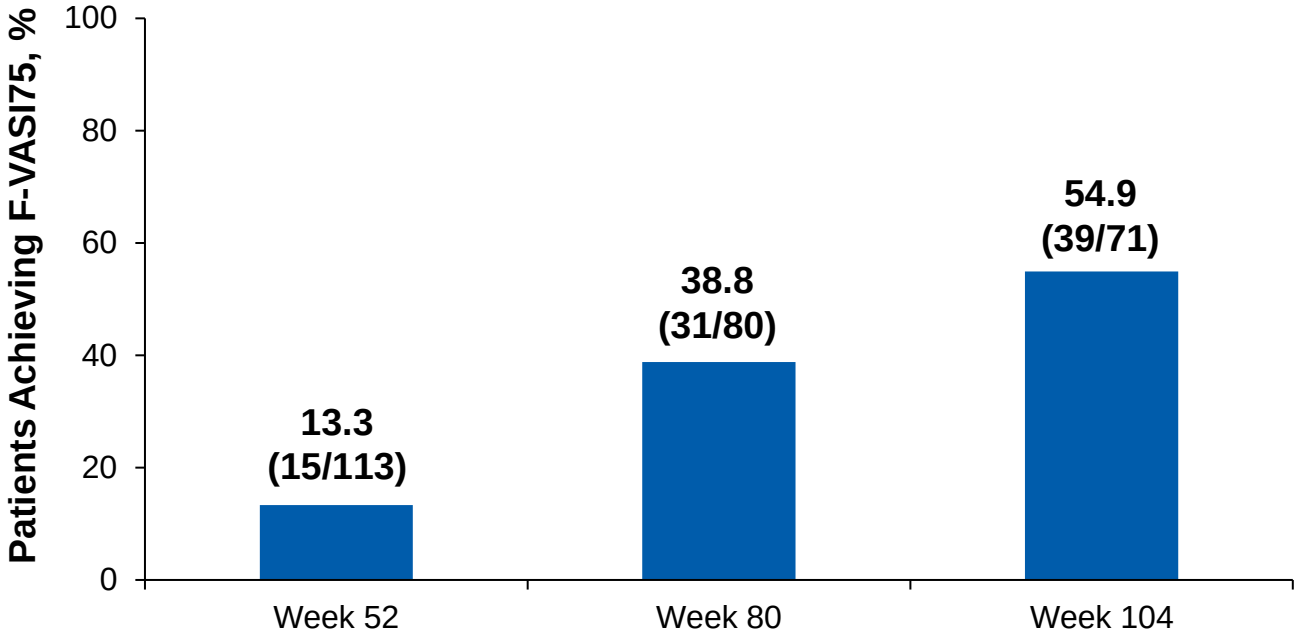
F-VASI75 Response at Weeks 52–104

Patients With No or Limited Facial Repigmentation† at Week 24*

- F-VASI75 increased from 13.3% at Week 52 to 54.9% at Week 104



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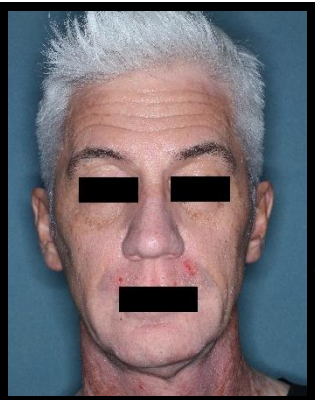
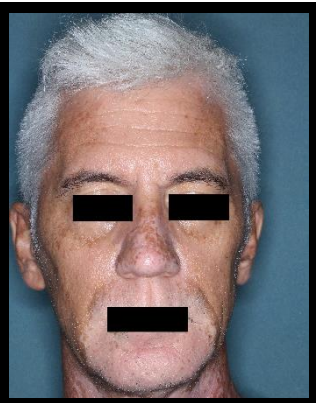
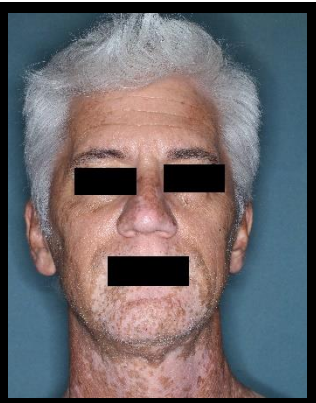
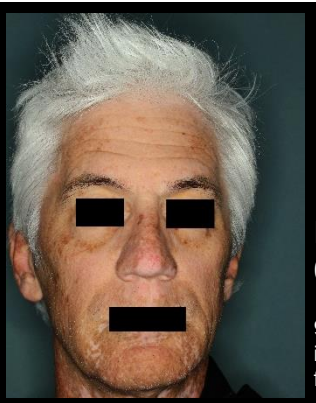
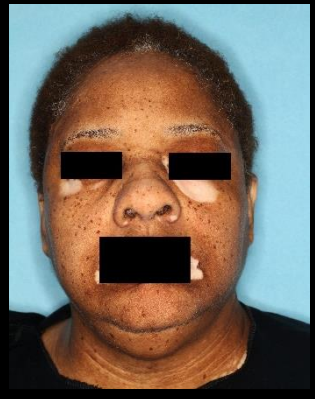
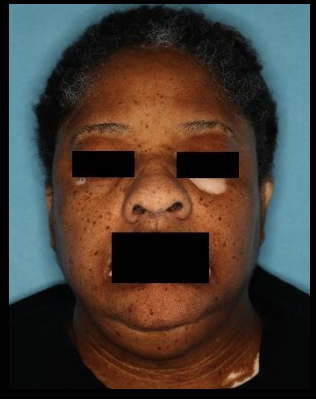
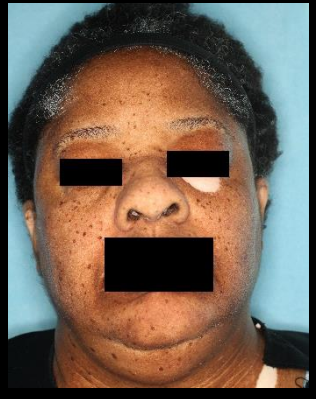
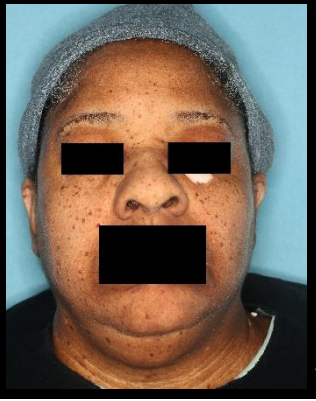
Clinical Images Showing F-VASI Response

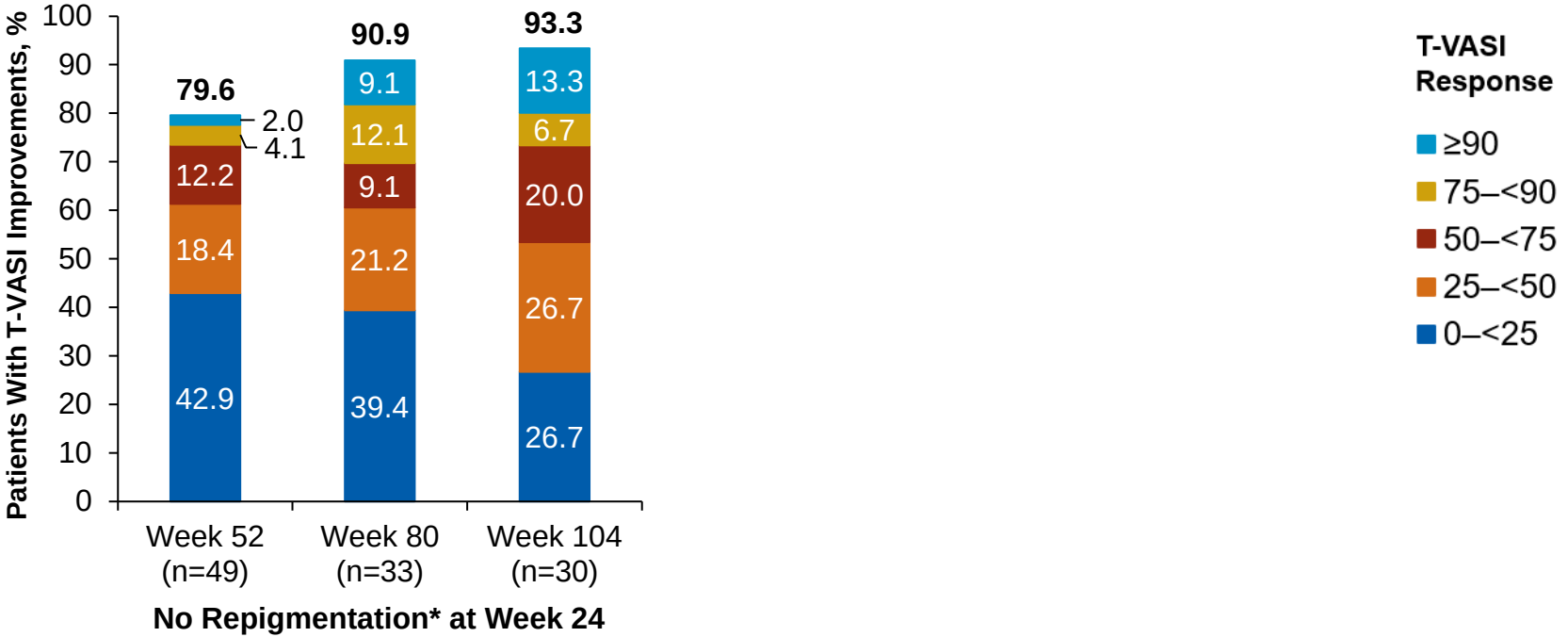
1.5% Ruxolitinib Cream BID

	Baseline	Week 24	Week 52	Week 104
Patient 1	 F-VASI, 0.50	 F-VASI, 0.40 20.0% improvement from baseline	 F-VASI, 0.25 50.0% improvement from baseline	 F-VASI, 0.03 94.0% improvement from baseline
Patient 2	 F-VASI, 0.70	 F-VASI, 0.63 10.0% improvement from baseline	 F-VASI, 0.31 55.7% improvement from baseline	 F-VASI, 0.09 87.1% improvement from baseline

T-VASI Response at Weeks 52–104

Patients With No or Limited Body Repigmentation at Week 24

- 68.8% and 84.9% of patients had T-VASI improvements at Weeks 52 and 104, respectively



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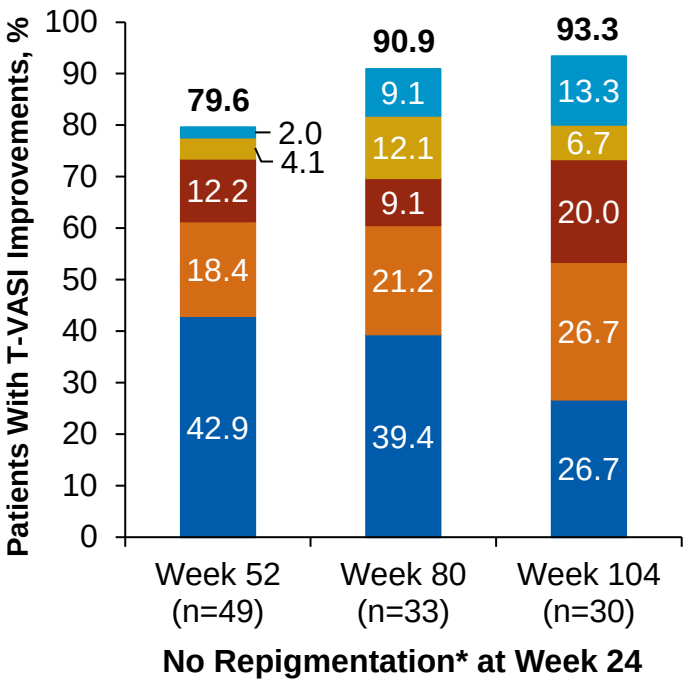
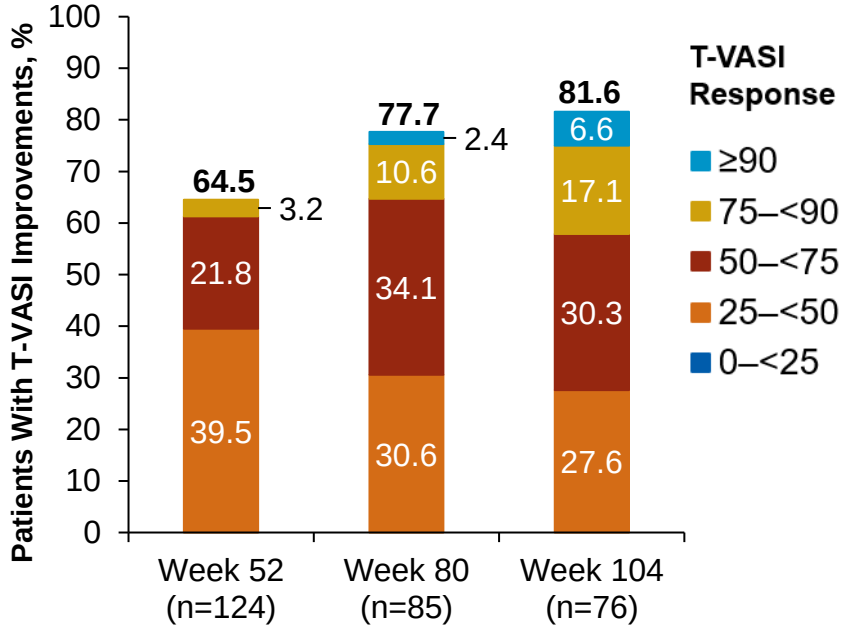


No Repigmentation* at Week 24



Limited Repigmentation† at Week 24

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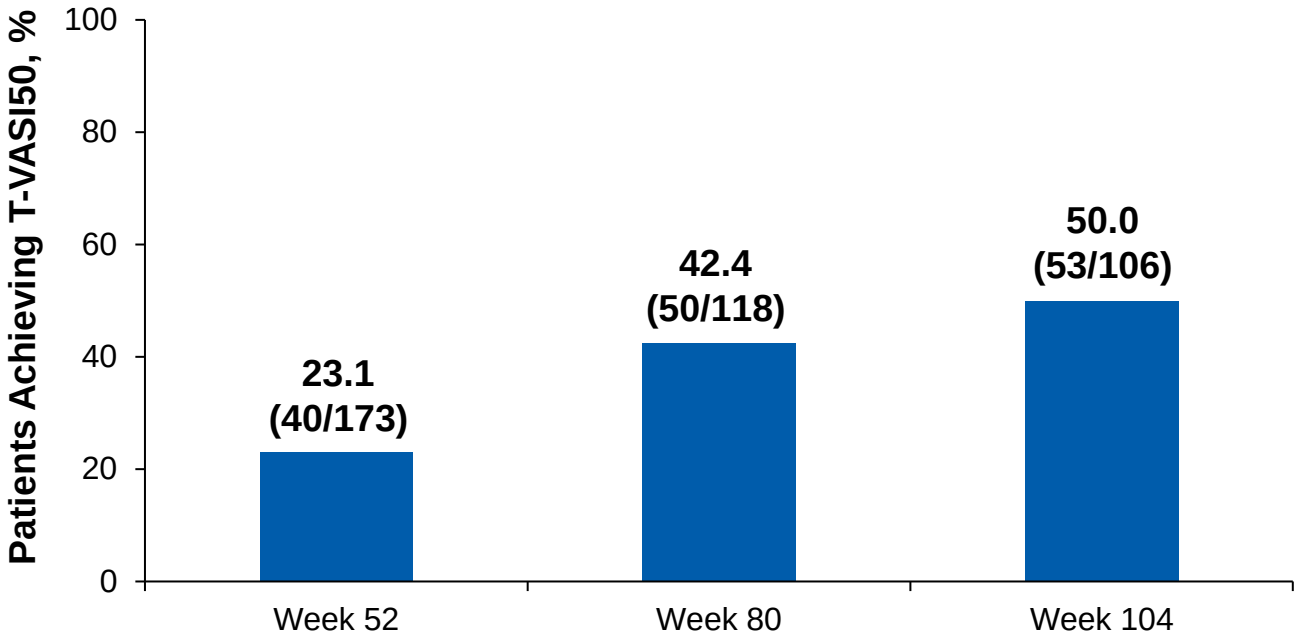
T-VASI50 Response at Weeks 52–104

Patients With No or Limited Body Repigmentation† at Week 24*

- T-VASI50 increased from 23.1% at Week 52 to 50.0% at Week 104



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Safety at Week 104

TRuE-V LTE Cohort B (<F-VASI90 at Week 52)

- Ruxolitinib cream was well tolerated over 104 weeks
- No serious treatment-related TEAEs occurred among patients who applied ruxolitinib cream from Day 1
- Application site pruritus (n=2; 0.9%) was the only treatment-related TEAE that occurred in >1 patient

Characteristic, n (%)	Ruxolitinib Cream From Day 1 (n=224)
Patients with ≥1 TEAE	114 (50.9)
Most common TEAEs*	
COVID-19	34 (15.2)
Nasopharyngitis	11 (4.9)
Urinary tract infection	7 (3.1)
Patients with ≥1 treatment-related TEAE	14 (6.3)
Patients with ≥1 application site reaction	19 (8.5)
Patients with ≥1 serious TEAE†	7 (3.1)
Patients with TEAE leading to discontinuation	0

TEAE, treatment-emergent adverse event.
* Occurring in ≥3% of patients.
† No serious TEAEs were considered by the investigators to be related to treatment.

Conclusions

- In vitiligo patients with minimal or no repigmentation at Week 24, 80 additional weeks of ruxolitinib cream application resulted in increased facial and body repigmentation in most patients
  - At Week 52, approximately 70% of patients had F-VASI or T-VASI improvements
  - At Week 104, approximately 85% of patients had F-VASI or T-VASI improvements, and approximately half of patients achieved F-VASI75 or T-VASI50
- These 2-year TRuE-V results highlight the importance of prolonged treatment in patients with vitiligo, even when limited or no repigmentation is achieved after 6 months of treatment