Characterizing Deep Quality-of-Life Response in the TRuE-V1/TRuE-V2 Studies of Ruxolitinib Cream in Nonsegmental Vitiligo

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Objective

- This post hoc analysis evaluated repigmentation characteristics of patients treated with ruxolitinib cream who achieved DLQI scores of 0 or 1, indicating no perceived burden of disease from the patient perspective and thus a deep QoL response

Conclusions

- **In the TRuE-V studies, nearly one-third of patients achieved a deep QoL response (DLQI 0/1) after 52 weeks of treatment, including a substantial proportion who did so despite achieving lower repigmentation thresholds (ie, <F-VASI50 or <T-VASI25)**
- **These findings show that patients in the TRuE-V studies who achieved a deep QoL response were represented across multiple repigmentation thresholds, suggesting that even partial repigmentation may deliver meaningful patient-perceived benefits**

Abbreviations

BSA, body surface area; DLQI, Dermatology Life Quality Index; F-BSA, facial BSA; F-VASI, facial Vitiligo Area Scoring Index; F-VASI25/50/75/90, ≥25%/50%/75%/90% improvement from baseline in F-VASI; QoL, quality of life; T-BSA, total BSA; T-VASI, total Vitiligo Area Scoring Index; T-VASI25/50/75/90, ≥25%/50%/75%/90% improvement from baseline in T-VASI.

Disclosures

SRD has received fees and/or honoraria as a consultant for Almirall, Avita, Bristol Myers Squibb, Cassiopea SpA, Dermavant Sciences, Dermira, Ferndale Laboratories, Foamix, Galderma Laboratories LP, Incyte, MC2 Therapeutics, Ortho Dermatologics, Pfizer, Scientis, Sente Labs, SkinCeuticals LLC, UCB, and Verrica Pharmaceuticals; has received stock options as a consultant for Gore Range Capital; has received honoraria as a speaker for Almirall and Ortho Dermatologics; has received grants/research funding as an investigator for AbbVie, AOBiome LLC, Atacama Therapeutics, Brickell Biotech, Dermavant Sciences, Incyte, Novan, and SkinMedica; has served as an advisory board member for the Foundation for Research & Education of Dermatology; is a stockholder of Gore Range Capital; and is a shareholder in PDP of Texas. **TP** has received grants and/or honoraria from AbbVie, ACM Pharma, Almirall, Amgen, Astellas, Bristol Myers Squibb, Calypso, Celgene, Galderma, Genzyme/Sanofi, GlaxoSmithKline, Incyte, Janssen, LEO Pharma, Eli Lilly, Novartis, Pfizer, Sun Pharmaceuticals, Takeda, UCB, and Vyne Therapeutics; is the cofounder of NIKAIA Pharmaceuticals; and has patents on WNT agonists or GSK3β antagonist for repigmentation of vitiligo and on the use of CXCR3B blockers in vitiligo. **PG** has served as a consultant for Aclaris Therapeutics, Clarify Medical, DermaForce, Incyte, Proctor & Gamble, and Versicolor Technologies; and a principal investigator for Aclaris Therapeutics, Allergan/SkinMedica, Clinuvel Pharmaceuticals, Incyte, Johnson & Johnson, L'Oreal, Merz Pharma, Pfizer, Thync Global Inc., and VT Cosmetics. **KE** is a consultant for AbbVie, Incyte, La Roche-Posay, Pfizer, Pierre Fabre, Sanofi, and Viela Bio. **JEH** has served as a consultant for AbbVie, Aldena Therapeutics, Almirall, Alys Pharmaceuticals, Avoro, Bain Capital, Granular Therapeutics, Incyte, Klirna, Matchpoint Therapeutics, NIRA Biosciences, TeVido BioDevices, Vimela Therapeutics, and Vividion; has served as an investigator for Barinthus Bio NA, Cour Pharma, Incyte, NextImmune, and TeVido BioDevices; holds equity in Aldena Therapeutics, Alys Pharmaceuticals, Incyte, NIRA Biosciences, Rheos Medicines, TeVido BioDevices, and Vimela Therapeutics; and is a scientific founder of Aldena Therapeutics, Alys Pharmaceuticals, Klirna, NIRA Biosciences, and Vimela Therapeutics. **AJM** has received research grants, royalties, and/or consulting support from a variety of companies, including Arcutis, Almirall, Abbvie, Apogee, Biersdorf, Bristol Meyers Squibb, Canfield, Concert, Dermavant, Eli Lilly, Galderma, Incyte, Kenvue, Janssen, Johnson & Johnson, L'Oreal, Leo, Nutrafol, Pelage, Pfizer, Procter and Gamble, Revian, Sanofi Regeneron, Sun Pharma, UCB, and Veradermics. **DS**, **XD**, and **HR** are employees and shareholders of Incyte. **DR** has received research support and honoraria (consultant/speaker) from AbbVie, Abcuro, Almirall, AltruBio, Amgen, Arena, Astria, Boehringer Ingelheim, Bristol Myers Squibb, Celgene, Concert, CSL Behring, Dermavant, Dermira, Dualitas, EMD Serono, Galderma, Incyte, Janssen, Kymera, Kyowa Kirin, Lilly, Merck, Nektar, Novartis, Pfizer, RAPT, Regeneron, Recludix, Revolo Biotherapeutics, Sanofi, Sun Pharmaceuticals, UCB, VielaBio, and Zura Bio.

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Introduction

- Vitiligo is a chronic, inflammatory autoimmune disease resulting in skin depigmentation that has a large impact on QoL[1,2]
- Ruxolitinib cream demonstrated statistically superior repigmentation rates vs vehicle at Week 24 in the phase 3 TRuE-V studies, with continued improvement through Week 52[3]
- Assessing treatment success in vitiligo is challenging because clinical repigmentation measures and patient-reported outcomes do not always align; achievement of DLQI 0/1 represents one approach to capture a deep, patient-perceived treatment benefit

Methods

- Patients enrolled in TRuE-V1/TRuE-V2 were aged ≥12 years and had nonsegmental vitiligo, including ≥0.5% facial BSA and ≥3% nonfacial BSA[3]
- This analysis included patients initially randomized to twice-daily 1.5% ruxolitinib cream with a DLQI Total Score ≥2 at baseline
  –DLQI has a score range of 0–30, where higher scores represent greater QoL impairment[5]
- Subgroups based on achievement of deep QoL response (ie, DLQI 0/1) at Weeks 24 and 52 were evaluated for clinical repigmentation response thresholds of F-VASI25/50/75/90 or T-VASI25/50/75/90

Results

- Despite having nonsegmental vitiligo, more than a quarter of patients in TRuE-V1/TRuE-V2 (28.4% [176/620]) reported no notable QoL burden from disease at baseline (ie, DLQI Total Score <2)
- Baseline demographics and clinical characteristics for the 290 patients randomized to ruxolitinib cream with DLQI Total Score ≥2 at baseline are shown in **Table 1**

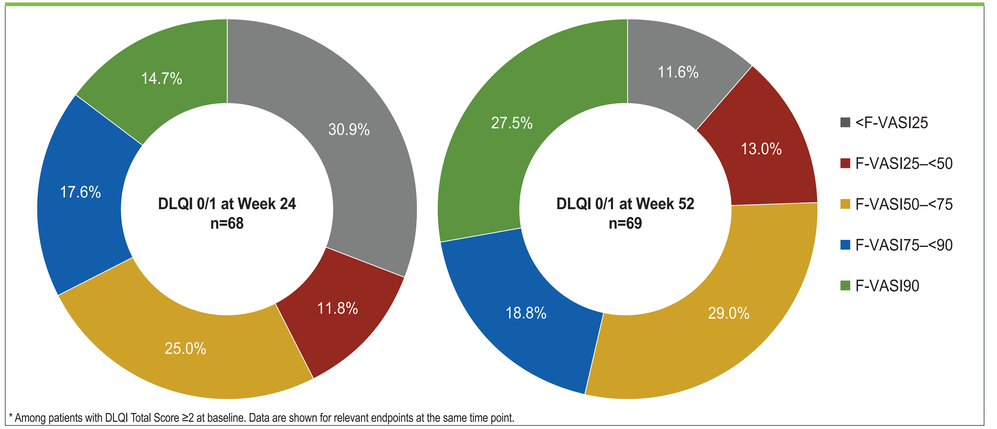
Table 1. Demographics and Clinical Characteristics for Patients With DLQI Total Score ≥2 at Baseline

Parameter	Patients (N=290)
Mean (SD) age, y	41.9 (13.5)
Female, n (%)	164 (56.6)
White, n (%)	242 (83.4)
Fitzpatrick skin type, n (%)	
I–III	216 (74.5)
IV–VI	74 (25.5)
F-BSA involvement, mean (SD), %*	1.1 (0.66)
T-BSA involvement, mean (SD), %*	7.3 (2.0)
F-VASI, mean (SD)	0.96 (0.59)
T-VASI, mean (SD)	6.6 (2.1)
Disease duration, mean (SD), y	15.5 (12.0)
Diagnosed in childhood, n (%)	87 (30.0)
Disease stability, n (%)	
Stable	218 (75.2)
Progressive†	72 (24.8)
Other autoimmune disorders, n (%)	65 (22.4)
Prior therapy,‡ n (%)	171 (59.0)
DLQI Total Score, mean (SD)	6.1 (4.4)

* Percentage of total BSA. † Patients with progressive vitiligo could have multiple phenotypes of disease activity; these included confetti lesions, trichrome lesions, inflammatory lesions, and Koebner phenomenon.
‡ Patients could have used multiple previous lines of therapy.

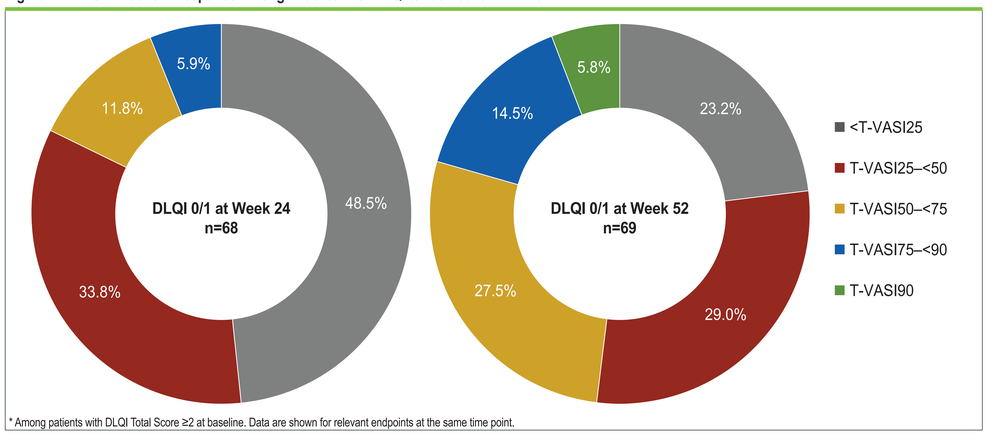
- Patients reported improved mean (SD) DLQI Total Scores at Week 24 (4.2 [3.9]) and Week 52 (4.2 [4.2]) versus baseline (6.1 [4.4]), with 26.3% and 30.8% achieving a deep QoL response per DLQI 0/1 at Weeks 24 and 52, respectively
- DLQI 0/1 was achieved across a range of repigmentation thresholds, including among patients who attained lower thresholds of facial and total body repigmentation (ie, <F-VASI25 or <T-VASI25; **Figures 1** and **2**)

Figure 1. F-VASI Threshold Response Among Patients With DLQI 0/1 at Weeks 24 and 52*



* Among patients with DLQI Total Score ≥2 at baseline. Data are shown for relevant endpoints at the same time point.

Figure 2. T-VASI Threshold Response Among Patients With DLQI 0/1 at Weeks 24 and 52*



* Among patients with DLQI Total Score ≥2 at baseline. Data are shown for relevant endpoints at the same time point.