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Vitiligo Noticeability Scale Score Maintenance or Shift During 52 Weeks of Ruxolitinib Cream Treatment for Vitiligo: Pooled Analysis of the TRuE-V Phase 3 Studies

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Introduction

- Vitiligo is a chronic autoimmune disease that targets melanocytes, resulting in patches of skin depigmentation[1]
- Disease pathogenesis is largely regulated by interferon-γ activation of the Janus kinase (JAK) signaling pathway[2]
- A cream formulation of ruxolitinib, a JAK1/JAK2 inhibitor, was recently approved by the US Food and Drug Administration for the topical treatment of nonsegmental vitiligo in adult and pediatric patients 12 years of age and older[3]
- In 2 randomized, double-blind, vehicle-controlled phase 3 studies of adults and adolescents with vitiligo (TRuE-V1 [NCT04052425]/TRuE-V2 [NCT04057573]), ruxolitinib cream was statistically superior to vehicle at Week 24 in the primary and all key secondary efficacy endpoints[4]

Objective

- To evaluate shifts (improvement or decrease) or stability in Vitiligo Noticeability Scale (VNS) response among patients who applied ruxolitinib cream for 52 weeks in TRuE-V1/TRuE-V2

Methods

Patients and Study Design

- For both studies, eligible patients were aged ≥12 years with a diagnosis of nonsegmental vitiligo and depigmented areas covering ≤10% total body surface area (BSA; facial and nonfacial), including ≥0.5% BSA on the face and ≥3% BSA on nonfacial areas, with scores ≥0.5 on facial Vitiligo Area Scoring Index (F-VASI) and ≥3 on total VASI (T-VASI)
- Key exclusion criteria and study design (**Figure 1**) were described previously[4]

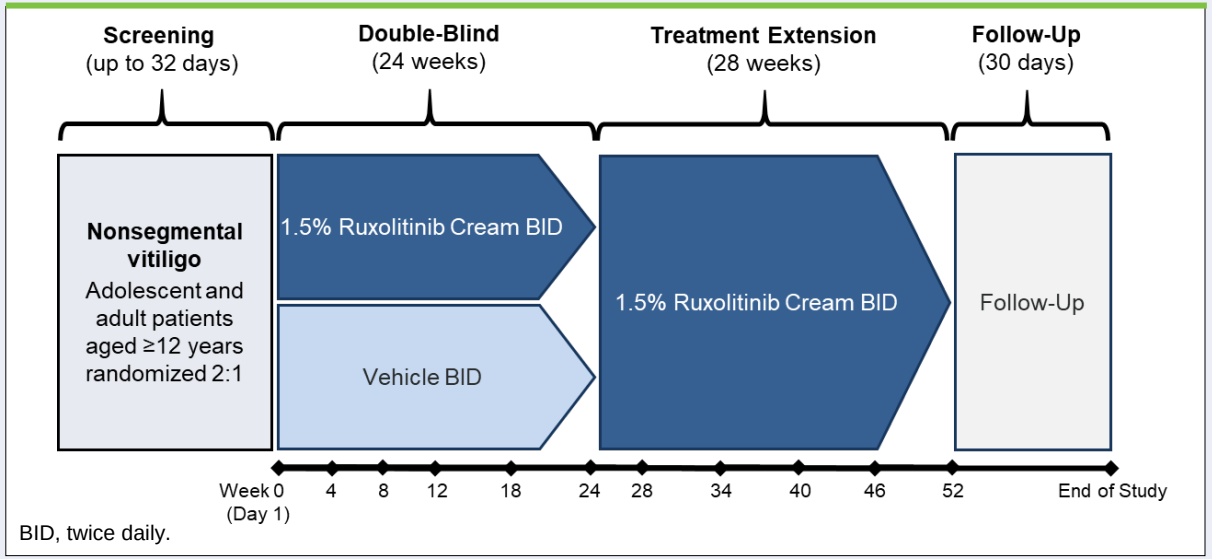
Endpoints and Assessments

- The VNS is a patient-reported measure of treatment success; patients were shown a baseline photograph and provided a mirror to assess how noticeable their facial vitiligo was at the study visit compared with baseline
  - The VNS has a 5-point scale: more noticeable (1), as noticeable (2), slightly less noticeable (3), a lot less noticeable (4), and no longer noticeable (5)
- The safety and tolerability of ruxolitinib cream were also assessed

Statistical Analyses

- Efficacy data at Weeks 12, 24, and 52 are reported as observed, and subgroup analyses were summarized using descriptive statistics
- All patients who applied ≥1 dose of study drug were included in the safety analysis

Figure 1. Study Design



BID, twice daily.

Results

Patients

- In total, 450 patients were randomized to apply ruxolitinib cream in the TRuE-V studies; 449 patients were included in the safety analysis
- In the ruxolitinib cream group, mean (SD) age at baseline was 39.4 (15.4) years, 44.8% of patients were male, 71.5% had Fitzpatrick skin types I–III, and median (range) duration of vitiligo was 11.9 (0–60.5) years
- Baseline mean (SD) F-VASI and T-VASI scores were 0.92 (0.55) and 6.67 (2.05), respectively

VNS Response Shifts or Stability

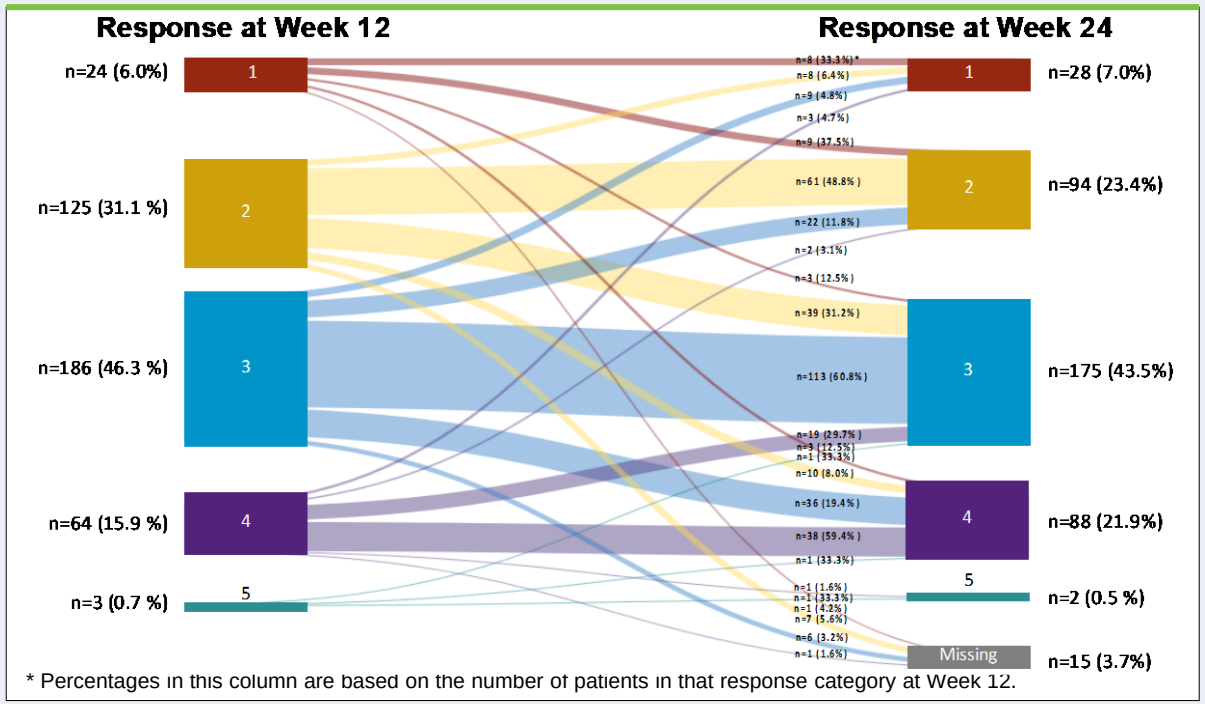
- In total, 402 patients who applied ruxolitinib cream from Day 1 had VNS evaluations at Week 12, of whom 16.7% achieved a VNS response of 4 (a lot less noticeable vs baseline) or 5 (no longer noticeable vs baseline; **Table 1**; **Figure 2**)
  - At Week 24, 25.1% thought their vitiligo was less noticeable, and therefore improved their response from Week 12
  - Over half (55.0%) thought their vitiligo had the same noticeability, thus remaining stable in their Week 12 response
  - 16.2% thought their vitiligo was more noticeable, indicating decreased response
  - 3.7% had missing evaluations

Table 1. VNS Response Shift From Week 12 to Week 24 of Treatment

Response	Response at Week 12, n (%)*	Response at Week 24, n (%)†					
		1	2	3	4	5	Missing
1	24 (6.0)	8 (33.3)	9 (37.5)	3 (12.5)	3 (12.5)	0	1 (4.2)
2	125 (31.1)	8 (6.4)	61 (48.8)	39 (31.2)	10 (8.0)	0	7 (5.6)
3	18 (46.3)	9 (4.8)	22 (11.8)	113 (60.8)	36 (19.4)	0	6 (3.2)
4	64 (15.9)	3 (4.7)	2 (3.1)	19 (29.7)	38 (59.4)	1 (1.6)	1 (1.6)
5	3 (0.7)	0	0	1 (33.3)	1 (33.3)	1 (33.3)	0
Total	401 (100)	28 (7.0)	94 (23.4)	175 (43.5)	88 (21.9)	3 (0.7)	15 (3.7)

VNS, Vitiligo Noticeability Scale.
1, more noticeable; 2, as noticeable; 3, slightly less noticeable; 4, a lot less noticeable; 5, no longer noticeable.
* Percentages based on evaluable patients at Week 12 (n=402).
† Percentages based on the number of patients in that response category at Week 12.

Figure 2. VNS Response Shift From Week 12 to Week 24 of Treatment



* Percentages in this column are based on the number of patients in that response category at Week 12.

Results *(cont.)*

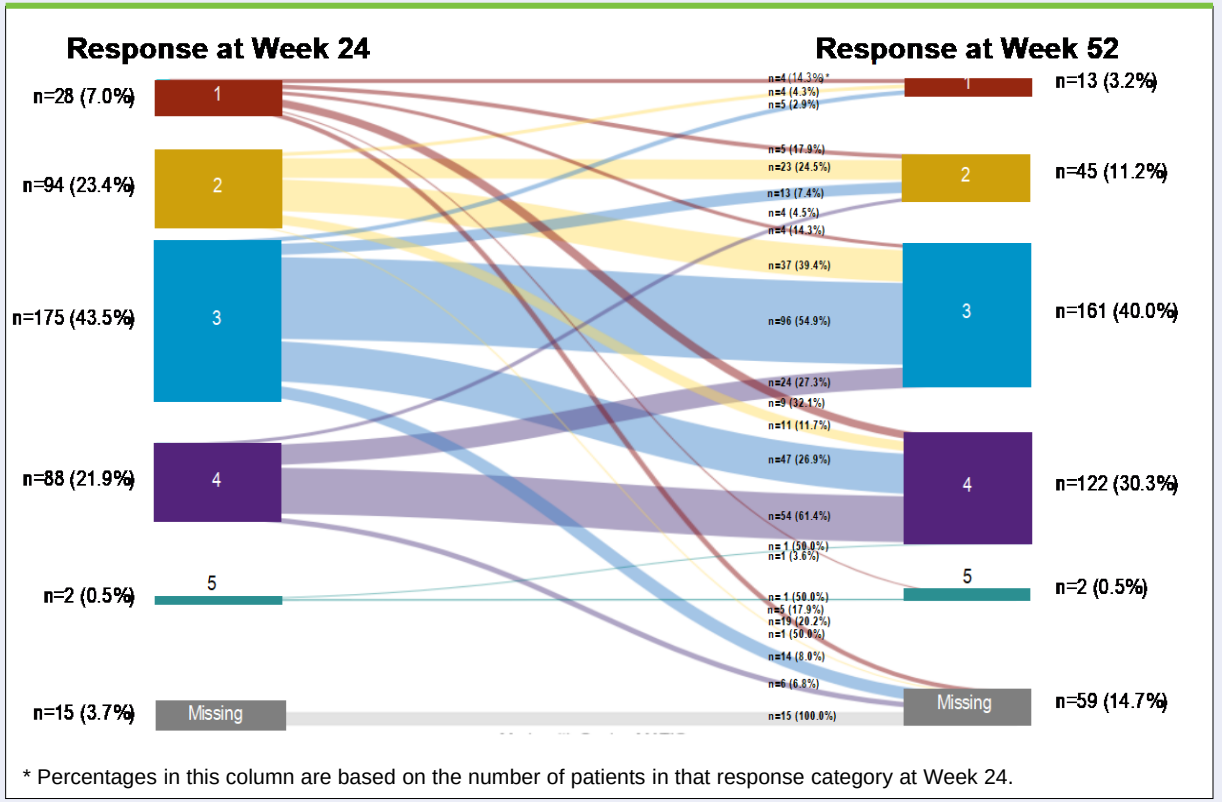
- At Week 24, 90 of 402 patients (22.4%) achieved a VNS response of 4 or 5 (**Table 2**; **Figure 3**), which was a key secondary endpoint
  - At Week 52, 28.4% of patients thought their vitiligo was less noticeable, and therefore improved their response from Week 24
  - At Week 52, 44.3% thought their vitiligo had the same noticeability, thus remaining stable in their Week 24 response
  - 12.7% thought their vitiligo was more noticeable, indicating decreased response
  - 14.7% had missing evaluations
- At Week 52, 124 of 402 patients (30.8%) thought their vitiligo was a lot less noticeable or no longer noticeable compared with baseline

Table 2. VNS Response Shift From Week 24 to Week 52 of Treatment

Response	Response at Week 24, n (%)*	Response at Week 52, n (%)†					
		1	2	3	4	5	Missing
1	28 (7.0)	4 (14.3)	5 (17.9)	4 (14.3)	9 (32.1)	1 (3.6)	5 (17.9)
2	94 (23.4)	4 (4.3)	23 (24.5)	37 (39.4)	11 (11.7)	0	19 (20.2)
3	175 (43.5)	5 (2.9)	13 (7.4)	96 (54.9)	47 (26.9)	0	14 (8.0)
4	88 (21.9)	0	4 (4.5)	24 (27.3)	54 (61.4)	0	6 (6.8)
5	2 (0.5)	0	0	0	1 (50.0)	1 (50.0)	0
Missing	15 (3.7)	0	0	0	0	0	15 (100)
Total	401 (100)	13 (3.2)	45 (11.2)	161 (40.0)	122 (30.3)	3 (0.5)	59 (14.7)

VNS, Vitiligo Noticeability Scale.
1, more noticeable; 2, as noticeable; 3, slightly less noticeable; 4, a lot less noticeable; 5, no longer noticeable.
* Percentages based on evaluable patients at Week 12 (n=402).
† Percentages based on the number of patients in that response category at Week 24.

Figure 3. Response Shift From Week 24 to Week 52 of Treatment



* Percentages in this column are based on the number of patients in that response category at Week 24.

Results *(cont.)*

Safety

- Ruxolitinib cream was well tolerated through 52 weeks of treatment
- A total of 58.6% of patients experienced ≥1 treatment-emergent adverse event (AE), most commonly COVID-19 (7.3%), application site acne (6.5%), nasopharyngitis (5.8%), and application site pruritus (5.3%)
- Application site reactions were the most common treatment-related AEs; these included acne (5.6%) and pruritus (4.7%), all of which were mild or moderate
- No serious AEs were considered related to treatment
- There were no clinically significant changes in hemoglobin or platelet levels

Conclusions

- **Adolescents and adults with nonsegmental vitiligo applying ruxolitinib cream largely thought that compared with baseline, their vitiligo was less noticeable or of similar noticeability from Week 12 to 24 and from Week 24 to 52 per pooled data from the TRuE-V1/TRuE-V2 phase 3 studies**
  - **A VNS response of 4 (a lot less noticeable) or 5 (no longer noticeable) was attained by 16.7% of patients at Week 12, 22.4% at Week 24, and 30.8% at Week 52**
- **Ruxolitinib was well tolerated, with no serious treatment-related AEs reported through 52 weeks**

Disclosures

KE is a consultant for AbbVie, Incyte Corporation, La Roche-Posay, Pfizer, Pierre Fabre, Sanofi, and Viela Bio. TP has received grants and/or honoraria from AbbVie, ACM Pharma, Almirall, Amgen, Astellas, Bristol Myers Squibb, Celgene, Galderma, Genzyme/Sanofi, GlaxoSmithKline, Incyte, Janssen, LEO Pharma, Eli Lilly, Novartis, Pfizer, Sun Pharmaceuticals, and UCB; is the cofounder of YUKIN Therapeutics; and has patents on WNT agonists or GSK3b antagonist for repigmentation of vitiligo and on the use of CXCR3B blockers in vitiligo. DR has received honoraria as a consultant for AbbVie, Abcuro, AltruBio, Boehringer Ingelheim, Bristol Myers Squibb, Celgene, Concert, Dermavant Sciences, Dermira, Incyte, Janssen, Kyowa Kirin, Lilly, Novartis, Pfizer, Regeneron Pharmaceuticals, Revolo Biotherapeutics, Sanofi, Sun Pharmaceuticals, UCB, and Viela Bio; has received research support from AbbVie, Amgen, Bristol Myers Squibb, Celgene, Dermira, Galderma, Incyte, Janssen, Lilly, Merck, Novartis, Pfizer, and Regeneron Pharmaceuticals; and has served as a paid speaker for AbbVie, Amgen, Celgene, Janssen, Lilly, Novartis, Pfizer, Regeneron Pharmaceuticals, and Sanofi. AGP has served as an investigator for Aclaris Therapeutics, Immune Tolerance Network, Incyte, and Pfizer; a consultant for AbbVie, Arcutis, Avita Medical, Chromaderm, Immune Tolerance Network, Incyte, Pfizer, TWi, Viela Bio, and Villaris; and holds stock options for Tara Medical and Zerigo Health. JS has received grants and/or honoraria from AbbVie, Bristol Myers Squibb, Calypso Biotech, Eli Lilly, Incyte, LEO Pharma, Novartis, Pfizer, Pierre Fabre, Sanofi, Sun Pharmaceuticals, and Viela Bio; and has patents on MMP9 inhibitors and uses thereof in the prevention or treatment of a depigmenting disorder and three-dimensional model of depigmenting disorder. DK, HR, KButler, and KBibeau are employees and shareholders of Incyte. 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.

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