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BRIEF REPORT

Efficacy and Safety of Ruxolitinib Cream in Vitiligo by Patient Characteristic Subgroups: Descriptive Pooled Analysis From Two Phase 3 Studies

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ABSTRACT

Introduction: Two phase 3 trials (TRuE-V1 and TRuE-V2) demonstrated that a topical formulation of the Janus kinase (JAK) 1/JAK2 inhibitor ruxolitinib significantly improved repigmentation versus vehicle cream in adolescent and adult patients with vitiligo. This post hoc analysis of pooled TRuE-V1/TRuE-V2 data evaluated efficacy and safety by baseline demographics and clinical characteristics.

Methods: Patients aged ≥ 12 years with nonsegmental vitiligo were randomized to vehicle cream or 1.5% ruxolitinib cream twice daily for 24 weeks, after which all patients could apply ruxolitinib cream through Week 52. Efficacy was evaluated using achievement of ≥ 75% improvement from baseline in facial Vitiligo Area Scoring Index [F-VASI75] at Week 52. Safety assessments included the frequency of treatment-emergent adverse events (AEs) and treatment-related AEs.

Results: The TRuE-V studies enrolled 674 patients. Week 52 F-VASI75 was achieved by 50.3% (176/350) of patients who applied ruxolitinib cream throughout and 28.2% (46/163) who crossed over from vehicle to ruxolitinib cream after Week 24. F-VASI75 responses were observed across subgroups regardless of patient

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age, sex, Fitzpatrick skin type, affected facial body surface area, disease duration, disease stability, and prior treatment status. Treatment-emergent AEs occurred in 52.1% (332/637) of patients, and treatment-related AEs occurred in 13.7% (87/637); rates were generally similar across demographic subgroups.

Conclusions: Adolescent and adult patients with vitiligo who applied ruxolitinib cream could achieve clinically meaningful repigmentation per F-VASI75 response at 1 year, regardless of their baseline demographics or clinical characteristics. Ruxolitinib cream was well tolerated, with a similar incidence of treatment-emergent and treatment-related AEs across subgroups.

Trial Registration: NCT04052425/NCT04057573.

PLAIN LANGUAGE SUMMARY

Vitiligo is a disease that causes white patches on the skin. Two large clinical trials, each 1 year long, showed that applying a topical treatment called ruxolitinib cream resulted in a return of skin color to white patches. The analysis described here used data from these two clinical trials to determine whether ruxolitinib cream is safe and effective for treating vitiligo in different subgroups of people with vitiligo. These subgroups were based on age, sex (men/women), and skin tone, as well as features of their disease, such as how long they had vitiligo. The authors found that ruxolitinib cream recolored white patches on the faces of many people who treated their skin for 1 year. This was true regardless of how old they were, whether they were men or women, and how fair or dark their skin was. This was also true regardless of differences in the disease, including whether they had vitiligo for a short or a long time, how much of their face was originally covered in white patches, if they had white patches that stayed the same or changed a lot before the trial, and whether they tried other treatments before. Ruxolitinib cream was previously shown to have generally mild side effects. Importantly, the authors here found that side effects did not differ between patient subgroups. These results show that ruxolitinib cream is an effective and safe option to treat vitiligo across a diverse population of patients.

Keywords: JAK inhibitor; Janus kinase; Repigmentation; Ruxolitinib cream; Topical; Vitiligo

Key Summary Points
Ruxolitinib cream was previously shown to provide superior repigmentation versus vehicle cream in two phase 3 studies of adolescents and adults with vitiligo
This pooled post hoc subgroup analysis evaluated facial repigmentation by baseline demographics and clinical characteristics in the two phase 3 studies
Half of patients applying ruxolitinib cream throughout achieved a ≥ 75% improvement from baseline in facial Vitiligo Area Scoring Index (F-VASI75) at Week 52
Patients who applied ruxolitinib cream could achieve clinically meaningful repigmentation per F-VASI75 response at 1 year, regardless of their baseline demographics or clinical characteristics
Ruxolitinib cream was well tolerated, with similar rates of adverse events across demographic subgroups

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INTRODUCTION

Treatment selection and outcomes for vitiligo, a chronic autoimmune skin disease, may be affected by demographic and clinical factors [1]. A cream formulation of ruxolitinib, a selective Janus kinase (JAK) 1/JAK2 inhibitor, is the first approved repigmentation treatment for vitiligo [2]. In two randomized, double-blind, vehicle-controlled phase 3 studies of adults and adolescents aged ≥ 12 years with nonsegmental vitiligo (TRuE-V1/TRuE-V2 [NCT04052425/NCT04057573]), ruxolitinib cream was statistically superior to vehicle at Week 24, with continued improvement observed through Week 52 [3]. Ruxolitinib cream was well tolerated, and application site reactions were mild or moderate [3]. In subanalyses from an earlier phase 2 study (NCT03099304), ruxolitinib cream produced clinically meaningful repigmentation regardless of baseline demographic and clinical characteristics among patients who achieved ≥ 50% improvement from baseline in facial Vitiligo Area Scoring Index (F-VASI; F-VASI50) [4].

Achieving ≥ 75% improvement from baseline in F-VASI (F-VASI75) [5], a clinically relevant threshold based on patients' perceptions of a meaningful improvement in their vitiligo, was the primary endpoint in TRuE-V1/TRuE-V2 [3, 5–7]. This post hoc analysis of pooled TRuE-V1/TRuE-V2 data evaluated efficacy, per F-VASI75, and safety of ruxolitinib cream according to demographics and clinical characteristic subgroups.

METHODS

The TRuE-V1/TRuE-V2 study design was previously reported; after a 24-week vehicle-controlled period, all patients could apply twice-daily 1.5% ruxolitinib cream for another 28 weeks [3]. At Week 52, patients were assessed for achievement of F-VASI75. Outcomes were evaluated by age group (12–17 years, 18–64 years, ≥ 65 years), sex (male, female), geographic region (North America, Europe), race (White, Black, Asian, other, not reported), Fitzpatrick skin type (I–III, IV–VI), facial body surface area (F-BSA; < 1.5%, ≥ 1.5%), investigator-assessed disease stability (stable, progressive), other autoimmune disorders (yes, no), disease duration (< 10 years, 10–20 years, > 20 years), and previous therapy (yes, no; topical corticosteroids, topical calcineurin inhibitors, phototherapy). Safety and tolerability assessments included frequency of reported treatment-emergent adverse events (AEs) and treatment-related AEs. All patients who applied ≥ 1 dose were included in the safety analysis. Data were pooled and reported as observed; subgroup analyses were summarized by descriptive statistics.

TRuE-V1/TRuE-V2 study protocols were approved by an institutional review board or ethics committee at each participating center. Both studies were conducted in accordance with the Declaration of Helsinki and adhered to Good Clinical Practice guidelines and applicable country-specific laws and regulations. All patients provided written informed consent or assent before study enrollment.

RESULTS

Overall, 674 patients were randomized in TRuE-V1/TRuE-V2 (ruxolitinib cream, $n = 450$; vehicle, $n = 224$), with 673 and 661 included in safety and efficacy analyses, respectively (Table 1), as previously reported [3]. Briefly, mean (SD) age at baseline was 39.5 (15.1) years; 27.9% (188/673) of patients had darker skin (Fitzpatrick skin types IV–VI). Baseline mean (SD) F-VASI score was 0.92 (0.56).

At Week 52, 50.3% (176/350) of patients applying ruxolitinib cream throughout achieved F-VASI75. Substantive F-VASI75 responses were achieved by patients regardless of subgroups analyzed (Fig. 1). F-VASI75 response rates were comparable among patients with lesions on less

Table 1 Patient demographics and disease characteristics

Characteristic	Vehicle (*n* = 224)	Ruxolitinib cream (*n* = 449)	Total (*N* = 673)
Age, mean (SD), years	39.7 (14.5)	39.4 (15.4)	39.5 (15.1)
Age group, *n* (%), years			
12–17	17 (7.6)	55 (12.2)	72 (10.7)
18–64	191 (85.3)	366 (81.5)	557 (82.8)
≥ 65	16 (7.1)	28 (6.2)	44 (6.5)
Sex, *n* (%)			
Male	114 (50.9)	201 (44.8)	315 (46.8)
Female	110 (49.1)	248 (55.2)	358 (53.2)
Geographic region, *n* (%)			
North America	156 (69.6)	307 (68.4)	463 (68.8)
Europe	68 (30.4)	142 (31.6)	210 (31.2)
Race, *n* (%)			
White	189 (84.4)	362 (80.6)	551 (81.9)
Black/African American	9 (4.0)	23 (5.1)	32 (4.8)
Asian	11 (4.9)	17 (3.8)	28 (4.2)
Other[a]	9 (4.0)	28 (6.2)	37 (5.5)
Not reported	6 (2.7)	19 (4.2)	25 (3.7)
Fitzpatrick skin type, *n* (%)			
I–III	164 (73.2)	321 (71.5)	485 (72.1)
IV–VI	60 (26.8)	128 (28.5)	188 (27.9)
F-BSA[b], mean (SD), %	1.03 (0.65)	1.02 (0.63)	1.02 (0.64)
< 1.5%[c], *n* (%)	179 (82.1)	355 (80.1)	534 (80.8)
≥ 1.5%[c], *n* (%)	39 (17.9)	88 (19.9)	127 (19.2)
Baseline F-VASI, mean (SD)	0.92 (0.56)	0.92 (0.55)	0.92 (0.56)
Baseline T-VASI, mean (SD)	6.73 (2.09)	6.67 (2.05)	6.69 (2.06)
Duration of disease, median (range), years	12.1 (0–59.5)	11.9 (0–60.5)	12.0 (0–60.5)
< 10 years[c], *n* (%)	88 (40.4)	197 (44.5)	285 (43.1)
10–20 years[c], *n* (%)	74 (33.9)	123 (27.8)	197 (29.8)
> 20 years[c], *n* (%)	56 (25.7)	123 (27.8)	179 (27.1)
Disease stability[d], (%)			
Stable	168 (75.0)	331 (73.7)	499 (74.1)

Table 1 continued

Characteristic	Vehicle ($n = 224$)	Ruxolitinib cream ($n = 449$)	Total ($N = 673$)
Progressive	56 (25.0)	118 (26.3)	174 (25.9)
Other autoimmune disorders, *n* (%)			
Yes	36 (16.1)	90 (20.0)	126 (18.7)
No	188 (83.9)	359 (80.0)	547 (81.3)
Previous therapy[e], *n* (%)			
Any	137 (61.2)	274 (61.0)	411 (61.1)
TCS	56 (25.0)	133 (29.6)	189 (28.1)
TCI	68 (30.4)	146 (32.5)	214 (31.8)
Phototherapy[f]	77 (34.4)	138 (30.7)	215 (31.9)
None	87 (38.8)	175 (39.0)	262 (38.9)

BSA body surface area, *F-BSA* facial body surface area, *F-VASI* facial Vitiligo Area Scoring Index, *NB-UVB* narrow-band ultraviolet-B, *PUVA* psoralen ultraviolet A, *TCI* topical calcineurin inhibitor, *TCS* topical corticosteroid, *T-VASI* total Vitiligo Area Scoring Index

[a]Includes American Indian/Alaska Native, Native Hawaiian/Pacific Islander, and "Other"

[b]Percentage of total BSA

[c]Among the intent-to-treat population (vehicle, $n = 218$; ruxolitinib cream, $n = 443$; total, $N = 661$)

[d]Determination of disease status was based on investigator judgment

[e]Patients could have used multiple previous lines of therapy

[f]Phototherapy includes NB-UVB phototherapy, excimer laser, and PUVA photochemotherapy

than half versus at least half of their face at baseline per F-BSA (< 1.5%, 49.1% [139/283]; ≥ 1.5%, 55.2% [37/67]), although the latter group's sample size was smaller. Response rates were consistent among patients with disease duration < 10 years (51.9% [82/158]) versus > 20 years (49.5% [47/95]), patients who had stable (49.4% [127/257]) versus progressive disease at baseline (52.7% [49/93]), and patients who were treatment-naive (48.1% [62/129]) versus previously treated (51.6% [114/221]). Response rates were numerically higher (≥ 10% difference) among female (55.2% [111/201]) versus male patients (43.6% [65/149]) and patients with darker (Fitzpatrick skin types IV–VI; 57.4% [58/101]) versus fairer skin (Fitzpatrick skin types I–III; 47.4% [118/249]). Trends toward lower F-VASI75 response rates were observed in patients aged ≥ 65 years (36.0% [9/25]) versus 12–17 years (48.0% [24/50]) and 18–64 years (52.0% [143/275]), although sample size was smaller in the ≥ 65 years age group. Furthermore, among patients crossing over from vehicle to ruxolitinib cream after Week 24 (28 weeks active treatment), 28.2% (46/163) achieved F-VASI75 at Week 52, with results largely consistent across reasonably sized subgroups (Fig. 2).

Among patients who applied ≥ 1 dose of ruxolitinib cream during TRuE-V1/TRuE-V2, any treatment-emergent AEs occurred in 52.1%

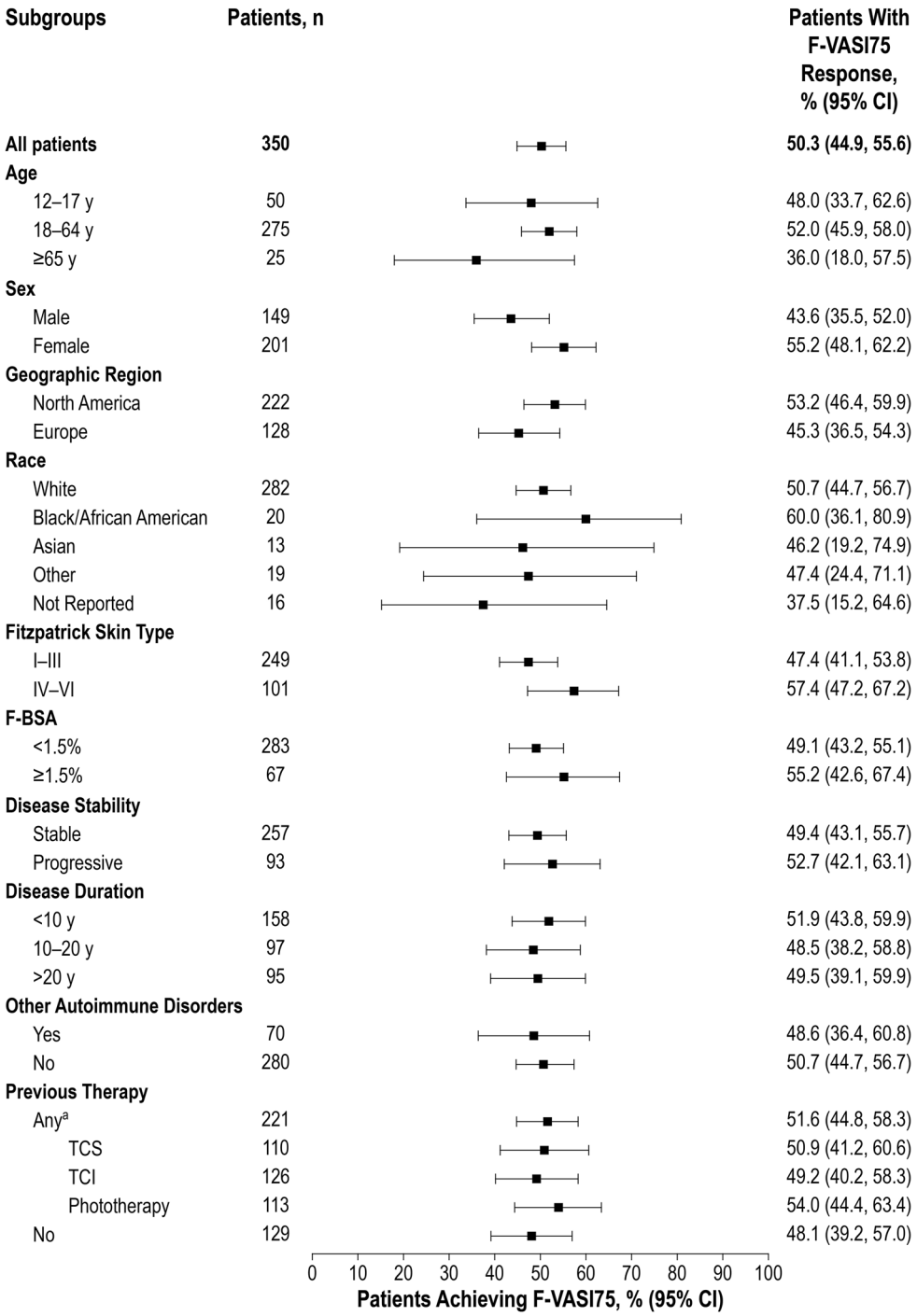

Fig. 1 F-VASI75 response at week 52 by patient demographics and baseline clinical characteristics among patients with vitiligo who applied ruxolitinib cream throughout (from day 1). [a]Patients could have used multiple previous lines of therapy. *F-BSA* facial body surface area, *F-VASI75* ≥ 75% improvement from baseline in facial Vitiligo Area Scoring Index, *TCI* topical calcineurin inhibitor, *TCS* topical corticosteroid

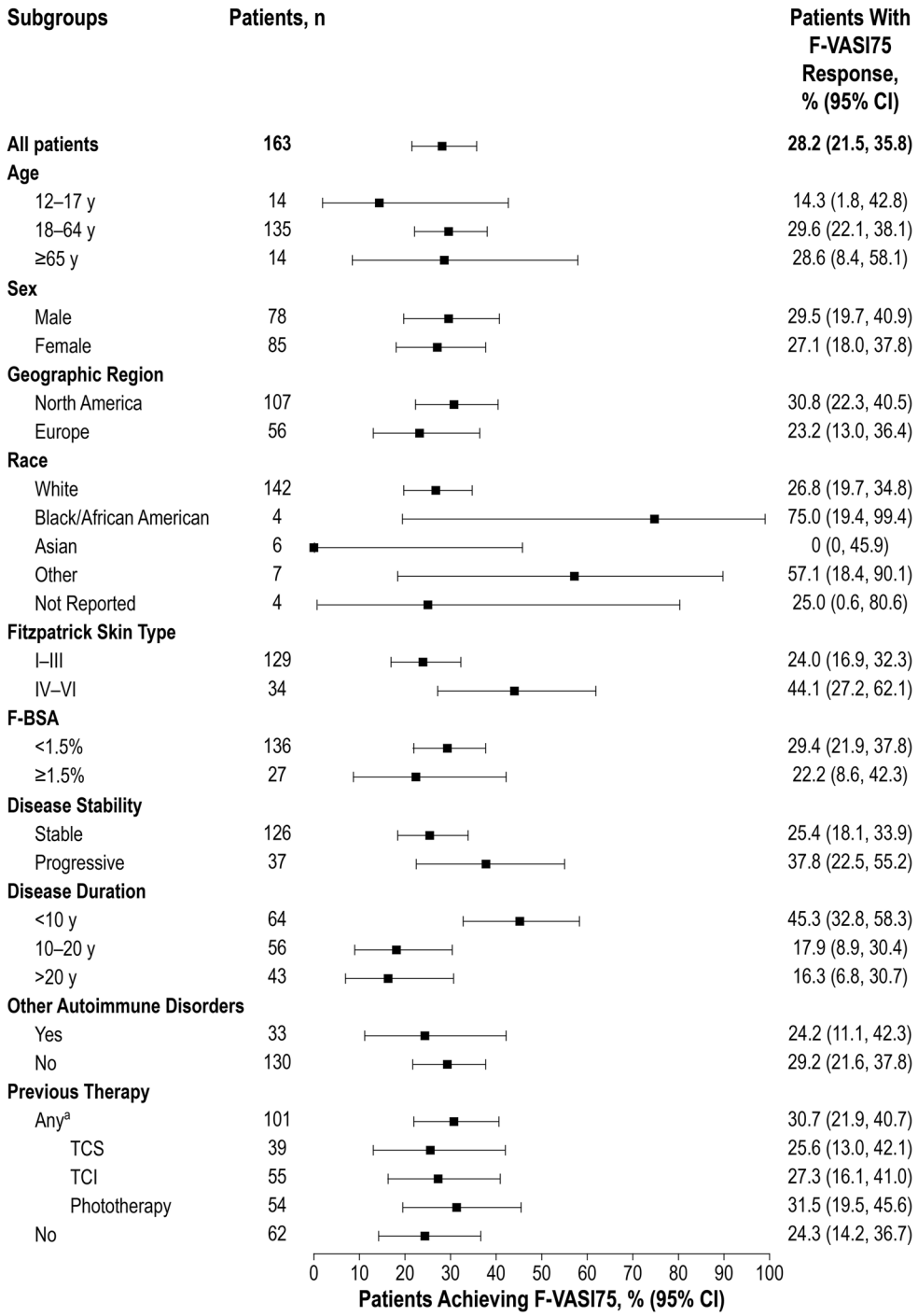

Fig. 2 F-VASI75 response at week 52 by patient demographics and baseline clinical characteristics among patients who crossed over from vehicle to ruxolitinib cream after week 24. [a]Patients could have used multiple previous lines of therapy. *F-BSA* facial body surface area, *F-VASI75* ≥ 75% improvement from baseline in facial Vitiligo Area Scoring Index, *TCI* topical calcineurin inhibitor, *TCS* topical corticosteroid

(332/637) of patients, and treatment-related AEs occurred in 13.7% (87/637), with generally similar rates among demographic and clinical characteristic subgroups (Table 2).

DISCUSSION

In this post hoc analysis of pooled data from the TRuE-V1/TRuE-V2 studies, approximately half of 350 patients applying ruxolitinib cream for 1 year achieved clinically meaningful facial repigmentation per F-VASI75 regardless of baseline demographics or clinical characteristics. Similarly, in those patients who crossed over from vehicle after Week 24, approximately 30% of 163 patients achieved F-VASI75 at Week 52, reflecting the shorter duration of ruxolitinib cream treatment for these patients (i.e., 28 weeks) than those who applied ruxolitinib cream throughout.

F-VASI75 response rates were comparable across subgroups of affected F-BSA, disease activity or disease duration, with similar outcomes in patients with short (< 10 years) versus long (> 20 years) disease duration, and regardless of prior vitiligo treatment. Importantly, patients with higher disease burden (i.e., female patients and those with darker skin) tended to have higher F-VASI75 response rates [8].

Results from this post hoc analysis of pooled data from the large phase 3 TRuE-V1/TRuE-V2 trials expand on findings from an earlier phase 2 study, which showed that approximately half of 33 patients who applied 1.5% ruxolitinib cream twice daily for 24 weeks achieved F-VASI50, regardless of patient subgroups [4]. F-VASI75 response, as assessed here, is accepted as treatment success for facial vitiligo [9]; thus, it is encouraging that ruxolitinib cream treatment displays efficacy among patients with varying demographics and clinical characteristics at baseline.

Furthermore, ruxolitinib cream is considered a safe treatment option for patients with vitiligo, as demonstrated in phase 2 and phase 3 trials [3, 10, 11]. These include a long-term safety analysis that showed no significant safety signals and no accumulation of AEs with application of ruxolitinib cream over 3 years [10]. Here, we confirm that ruxolitinib cream was well tolerated among 673 patients who applied treatment for up to 1 year, regardless of their demographic or clinical characteristic subgroups. Overall, these safety findings may be reassuring for patients likely to be encountered in real-world practice.

Limitations of this analysis include its exploratory post hoc design, small sample sizes in some subgroups, and lack of multiplicity adjustment, which limit meaningful interpretation and generalizability. Moreover, this analysis was performed using pooled data from the TRuE-V1/TRuE-V2 clinical trials, which may not be generalizable to real-world settings. The trends identified here may require confirmation in studies evaluating larger, real-world patient populations. Patient-reported outcomes and quality-of-life data were not included in this analysis but may be of value in future analyses as important measures of treatment efficacy. Finally, data presented here are limited to outcomes at Week 52; additional longer-term follow-up will improve our understanding of repigmentation maintenance with prolonged ruxolitinib cream application.

CONCLUSIONS

Adolescent and adult patients with vitiligo applying ruxolitinib cream could achieve efficacy per F-VASI75 response at 1 year regardless of demographics or clinical characteristics, confirming earlier phase 2 findings [4]. Ruxolitinib cream was well tolerated, with a similar incidence of treatment-emergent and treatment-related AEs across subgroups.

Table 2 TEAEs by demographic and baseline clinical characteristic subgroup

	Vehicle up to week 24			Ruxolitinib cream up to week 52[a]		
Subgroup, *n* (%)	***n***	**TEAE**	**TRAE**	***n***	**TEAE**	**TRAE**
All patients	224	81 (36.2)	16 (7.1)	637	332 (52.1)	87 (13.7)
Age groups, years						
12–17	17	6 (35.3)	0	70	37 (52.9)	9 (12.9)
18–64	191	66 (34.6)	13 (6.8)	525	275 (52.4)	73 (13.9)
≥ 65	16	9 (56.3)	3 (18.8)	42	20 (47.6)	5 (11.9)
Sex						
Male	114	31 (27.2)	3 (2.6)	293	140 (47.8)	33 (11.3)
Female	110	50 (45.5)	13 (11.8)	344	192 (55.8)	54 (15.7)
Geographic region						
North America	156	48 (30.8)	12 (7.7)	432	199 (46.1)	55 (12.7)
Europe	68	33 (48.5)	4 (5.9)	205	133 (64.9)	32 (15.6)
Race						
White	189	69 (36.5)	13 (6.9)	526	276 (52.5)	68 (12.9)
Black/African American	9	1 (11.1)	0	28	10 (35.7)	2 (7.1)
Asian	11	0	0	23	7 (30.4)	3 (13.0)
Other[b]	9	6 (66.7)	2 (22.2)	35	18 (51.4)	3 (8.6)
Not reported	6	5 (83.3)	1 (16.7)	25	21 (84.0)	11 (44.0)
Fitzpatrick skin type						
I–III	164	63 (38.4)	14 (8.5)	462	243 (52.6)	67 (14.5)
IV–V	60	18 (30.0)	2 (3.3)	175	89 (50.9)	20 (11.4)
F-BSA						
< 1.5%	185	62 (33.5)	14 (7.6)	516	257 (49.8)	66 (12.8)
≥ 1.5%	39	19 (48.7)	2 (5.1)	121	75 (62.0)	21 (17.4)
Disease stability						
Stable	168	57 (33.9)	11 (6.5)	473	243 (51.4)	58 (12.3)
Progressive	56	24 (42.9)	5 (8.9)	164	89 (54.3)	29 (17.7)
Disease duration, years						
< 10	92	31 (33.7)	6 (6.5)	269	141 (52.4)	34 (12.6)
10–20	75	28 (37.3)	6 (8.0)	190	96 (50.5)	27 (14.2)
> 20	57	22 (38.6)	4 (7.0)	178	95 (53.4)	26 (14.6)

Table 2 continued

Subgroup, *n* (%)	Vehicle up to week 24			Ruxolitinib cream up to week 52[a]		
	n	TEAE	TRAE	*n*	TEAE	TRAE
Other autoimmune disorders						
Yes	36	20 (55.6)	5 (13.9)	125	63 (50.4)	18 (14.4)
No	188	61 (32.4)	11 (5.9)	512	269 (52.5)	69 (13.5)
Previous therapy						
Any	137	54 (39.4)	12 (8.8)	386	208 (53.9)	53 (13.7)
TCS	56	21 (37.5)	6 (10.7)	175	91 (52.0)	30 (17.1)
TCI	68	29 (42.6)	4 (5.9)	207	114 (55.1)	33 (15.9)
Phototherapy	77	26 (33.8)	4 (5.2)	200	111 (55.5)	33 (16.5)
None	87	27 (31.0)	4 (4.6)	251	124 (49.4)	34 (13.5)

F-BSA facial body surface area, *TCI* topical calcineurin inhibitors, *TCS* topical corticosteroids, *TEAE* treatment-emergent adverse event, *TRAE* treatment-related adverse event

[a]Including patients who crossed over from vehicle after Week 24

[b]Includes patients who self-reported as American Indian/Alaska Native or Native Hawaiian/Pacific Islander

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Data Availability. Incyte Corporation (Wilmington, DE, USA) is committed to data sharing that advances science and medicine while protecting patient privacy. Qualified external scientific researchers may request anonymized datasets owned by Incyte for the purpose of conducting legitimate scientific research. Researchers may request anonymized datasets from any interventional study (except Phase 1 studies) for which the product and indication have been approved on or after 1 January 2020 in at least one major market (e.g., US, EU, JPN). Data will be available for request after the primary publication or 2 years after the study has ended. Information on Incyte's clinical trial data sharing policy and instructions for submitting clinical trial data requests are available at: https://www.incyte.com/Portals/0/Assets/Compliance%20and%20Transparency/clinical-trial-data-sharing.pdf?ver=2020-05-21-132838-960.

Declarations

Conflicts of Interest. Julien Seneschal 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. Albert Wolkerstorfer has served as principal investigator for AbbVie, Avita Medical, Incyte, Novartis, and MSD; has served as an advisory board member for Incyte; has received research grants from Avita Medical and Lumenis; and has received devices from Humeca and PerfAction. Seemal R. Desai 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. Pearl Grimes 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. Khaled Ezzedine is a consultant for AbbVie, Incyte, La Roche-Posay, Pfizer, Pierre Fabre, Sanofi, and Viela Bio. Amit G. Pandya 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. Deanna Kornacki and Shaoceng Wei are employees and shareholders of Incyte. Thierry Passeron 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, 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. David Rosmarin has received honoraria as a consultant or speaker, or for conducting clinical trials, for AbbVie, Abcuro, Almirall, AltruBio, Amgen, Arena Pharmaceuticals, Astria, Boehringer Ingelheim, Bristol Myers Squibb, Celgene, Concert, CSL Behring, Dermavant Sciences, Dermira, Dualitas Therapeutics, EMD Serono, Galderma, Incyte, Janssen, Kymera, Kyowa Kirin, Lilly, Merck, Nektar Therapeutics, Novartis, Pfizer, RAPT Therapeutics, Regeneron Pharmaceuticals, Recludix, Revolo Biotherapeutics, Sanofi, Sun Pharmaceuticals, UCB, Viela Bio, and Zura 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.

Ethical approval. TRuE-V1 and TRuE-V2 study protocols were approved by an institutional review board or ethics committee at each participating center. Both studies were conducted in accordance with the Declaration of Helsinki and adhered to Good Clinical Practice guidelines and applicable country-specific laws and regulations. All patients provided written informed consent or assent before study enrollment.

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