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Efficacy and Safety of Ruxolitinib Cream for the Treatment of Vitiligo Through 2 Years in the TRuE-V Studies

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Objective

- To evaluate ruxolitinib cream treatment through 2 years in the TRuE-V LTE study based on initial randomization in TRuE-V1/TRuE-V2

Conclusions

- **Ruxolitinib cream produced continued improvement of repigmentation through 2 years, both among patients who applied ruxolitinib cream from Day 1 and among those who crossed over from vehicle to ruxolitinib cream after 6 months**
- **Higher repigmentation rates were observed with longer duration of ruxolitinib cream treatment regardless of the initial treatment applied, although response rates were lower among patients who applied vehicle for the first 6 months**
- **Ruxolitinib cream was generally well tolerated through 2 years of treatment**

Abbreviations

BID, twice daily; DBVC, double-blind vehicle-controlled; EOS, end of study; F-VASI75/90, ≥75/90% improvement from baseline in facial VASI; JAK, Janus kinase; LTE, long-term extension; OLE, open-label extension; RUX-RUX, ruxolitinib cream from Day 1; TEAE, treatment-emergent adverse event; TRuE-V, Topical Ruxolitinib Evaluation in Vitiligo; T-VASI50, ≥50% improvement from baseline in total VASI; VASI, Vitiligo Area Scoring Index; VEH-RUX, vehicle to ruxolitinib cream after Week 24.

Disclosures

JLLE has participated in advisory boards for AbbVie, Janssen, Galderma, Incyte, Bioderma, Isdin, Novartis, and UCB. **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, NexImmune, 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. **KE** is a consultant for AbbVie, Incyte, La Roche-Posay, Pfizer, Pierre Fabre, Sanofi, and Viela Bio. **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. **KAP** has received honoraria or clinical research grants as a consultant, speaker, scientific officer, advisory board member, and/or steering committee member for AbbVie, Acelyrin, Akros, Alumis, Amgen, Arcutis, Bausch Health/Valeant, Boehringer Ingelheim, Bristol Myers Squibb, Can-Fite Biopharma, Celltrion, Concert Pharmaceuticals, CorEvitas, Dermavant, Dermira, Dice Pharmaceuticals, Eli Lilly, Evelo Biosciences, Forbion, Galderma, Horizon Therapeutics, Incyte, Janssen, Kymab, Kyowa Hakko Kirin, LEO Pharma, Meiji Seika Pharma, Mitsubishi Pharma, Nimbus Therapeutics, Novartis, Pfizer, Reistone, Sanofi-Aventis/Genzyme, Sandoz, Sun Pharmaceuticals, Takeda, Tarsus Pharmxueticals, UCB, and Zai Lab. **AW** is a consultant for AbbVie, Avita Medical, Incyte, MSD, and Novartis; 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. **HR** and **DK** are employees and shareholders of Incyte. **DR** has received honoraria as a consultant for AbbVie, Abcuro, Almirall, AltruBio, Arena, Astria, Boehringer-Ingelheim, Bristol Myers Squibb, Celgene, Concert, CSL Behring, Dermavant, Dermira, Incyte, Janssen, Kymera, Kyowa Kirin, Lilly, Nektar, Novartis, Pfizer, RAPT, Regeneron, Recludix, Revolo Biotherapeutics, Sanofi, Sun Pharmaceuticals, UCB, VielaBio, Zura Bio; has received research support from AbbVie, Amgen, Bristol Myers Squibb, Celgene, Dermira, Galderma, Incyte, Janssen, Lilly, Merck, Nektar, Novartis, Pfizer, RAPT, and Regeneron Pharmaceuticals Inc; and has served as a paid speaker for AbbVie, Amgen, Bristol Myers Squibb, Celgene, Dermavant, Incyte, Janssen, Lilly, Novartis, Pfizer, Regeneron Pharmaceuticals Inc., and Sanofi.

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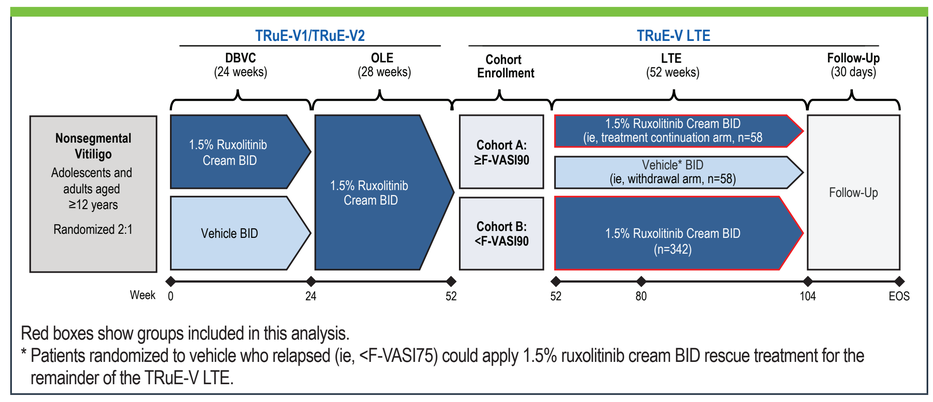
Introduction

- Vitiligo is a chronic autoimmune disease that targets melanocytes, causing skin depigmentation[1]
- Ruxolitinib, a JAK1/JAK2 inhibitor,[2] cream demonstrated statistically superior repigmentation vs vehicle at Week 24, with continued improvement through Week 52 in the phase 3 TRuE-V1/TRuE-V2 studies[3]

Methods

- TRuE-V LTE (NCT04530344) was a rollover randomized withdrawal and treatment-extension study enrolling patients who completed TRuE-V1/TRuE-V2 (NCT04052425/NCT04057573; **Figure 1**)
- This post hoc analysis determined the efficacy (facial and total VASI milestones) of ruxolitinib cream application through 2 years in the TRuE-V1/TRuE-V2[3] and TRuE-V LTE studies by initial randomization on Day 1; safety was assessed in all patients who applied ruxolitinib cream regardless of initial randomization

Figure 1. Study Design: Randomized Phase 3 Clinical Trials



Red boxes show groups included in this analysis.
* Patients randomized to vehicle who relapsed (ie, <F-VASI75) could apply 1.5% ruxolitinib cream BID rescue treatment for the remainder of the TRuE-V LTE.

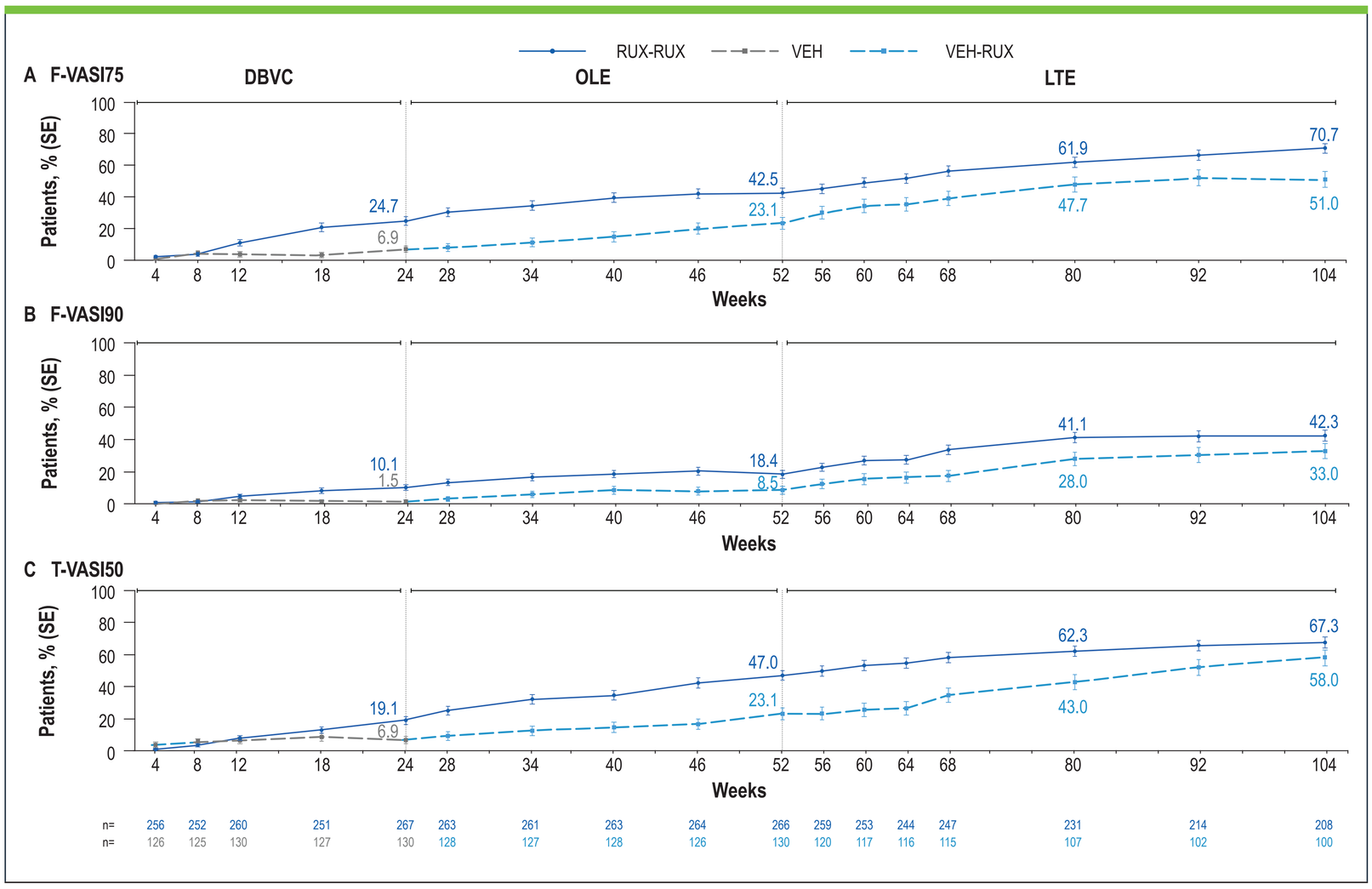
Results

- The analysis included 400 patients who applied ruxolitinib cream in the TRuE-V LTE, including 270 patients in the RUX-RUX group and 130 patients in the VEH-RUX group

Efficacy

- The percentage of patients achieving efficacy response milestones (F-VASI75, F-VASI90, and T-VASI50) increased steadily through 2 years of treatment, although response rates were lower for patients initially randomized to vehicle (**Figure 2**)

Figure 2. Response Rates for Facial and Total VASI Milestones Through 2 Years (ITT Population)



Safety

- Ruxolitinib cream was generally well tolerated through 2 years of treatment (**Table 1**)
- The most common TEAEs occurring with application of ruxolitinib cream were COVID-19 (81/400; 20.3%), nasopharyngitis (38/400; 9.5%), upper respiratory tract infection (26/400; 6.5%), application site acne (25/400; 6.3%), and headache (23/400; 5.8%)

Table 1. TEAEs Among Patients Through 2 Years (Safety Population)

Parameter, n (%)	Ruxolitinib cream (N=400)
Patients with TEAE	285 (71.3)
Patients with treatment-related TEAE	67 (16.8)
Most common treatment-related TEAEs*	
Application site acne	20 (5.0)
Application site pruritus	18 (4.5)
Application site dermatitis	7 (1.8)
Application site rash	7 (1.8)
Application site erythema	4 (1.0)
Application site pain	4 (1.0)
Application site discoloration	3 (0.8)
Application site exfoliation	3 (0.8)
Application site dryness	2 (0.5)
Application site folliculitis	2 (0.5)
Headache	2 (0.5)
Upper respiratory tract infection	2 (0.5)
Patients with application site reactions	67 (16.8)
Patients with serious TEAE†	19 (4.8)
Patients with grade ≥3 TEAE†	24 (6.0)
Patients with TEAE leading to discontinuation	1 (0.3)
Patients with TEAE leading to dose reduction	4 (1.0)

* Occurring in ≥2 patients.
† No serious or grade ≥3 TEAEs occurred in >1 patient.