

LETTER TO THE EDITOR

Prolonged ruxolitinib cream treatment for vitiligo among patients with no or limited response in the first 6 months

Dear Editor,

Ruxolitinib cream, a topical formulation of the Janus kinase (JAK) 1/JAK2 inhibitor ruxolitinib, is the first approved repigmentation therapy for nonsegmental vitiligo.¹ In two phase 3 clinical trials in adults and adolescents (aged ≥ 12 y) with vitiligo (TRuE-V1/TRuE-V2, NCT04052425/NCT04057573), ruxolitinib cream was associated with substantial repigmentation and was well tolerated over 52 weeks.² Further improvements in facial and body repigmentation were observed over 104 weeks in the TRuE-V

long-term extension study (TRuE-V LTE; NCT04530344).³ Repigmentation is a slow process that requires continuous treatment even if results are not immediately apparent.^{4,5} Vitiligo is associated with substantial psychosocial burden,⁶ which may be intensified by prolonged treatment requirements and delayed repigmentation.^{7,8} Here, efficacy and safety of continuous ruxolitinib cream treatment over 104 weeks were evaluated among patients who had no or limited response to treatment at Week 24 in TRuE-V1/TRuE-V2.

A. No Repigmentation* at Week 24 (n=70)

B. Limited Repigmentation† at Week 24 (n=57)

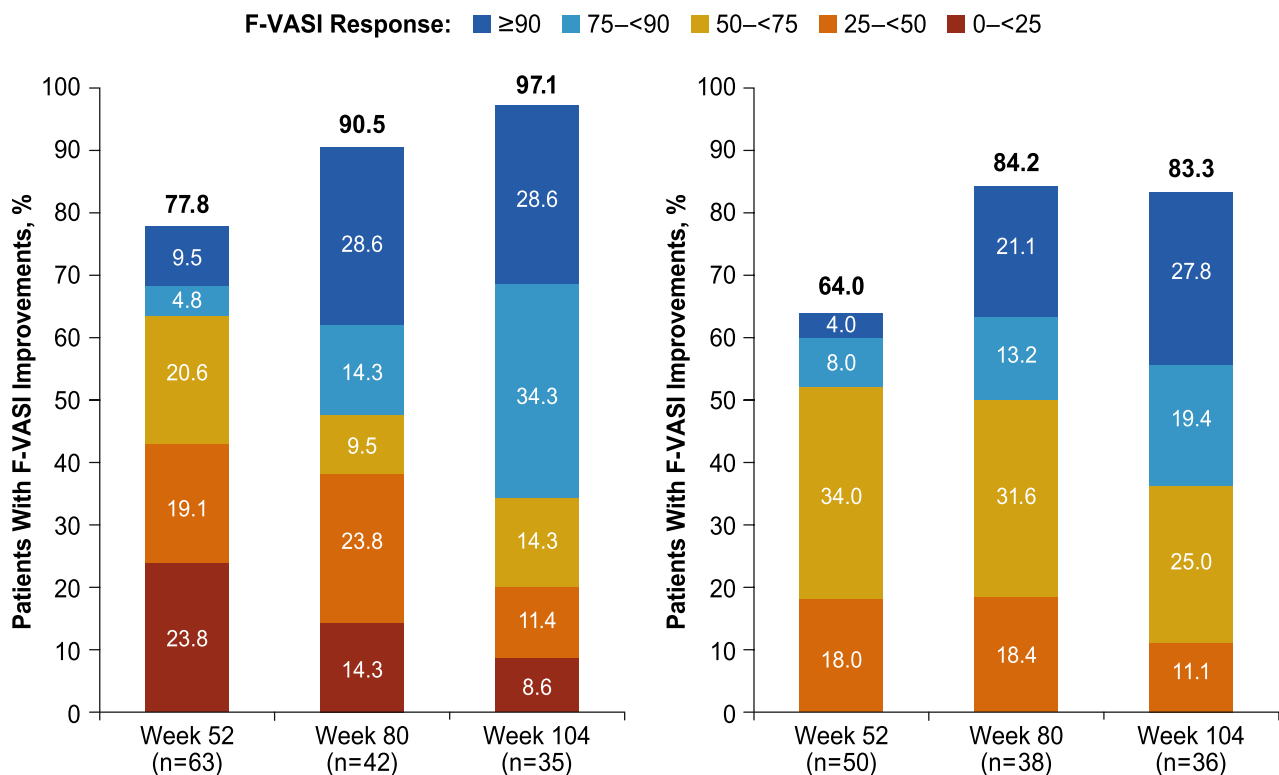


FIGURE 1 F-VASI response at Weeks 52, 80 and 104 among patients with continuous ruxolitinib cream treatment who had (a) no or (b) limited facial repigmentation at Week 24. F-VASI, Facial Vitiligo Area Scoring Index. *Patients with worsening or no improvement in F-VASI (i.e. $\leq 0\%$) at Week 24 and non-missing F-VASI values at Weeks 52, 80 or 104. †Patients with $>0\%$ –<25% improvement in F-VASI at Week 24 and non-missing F-VASI values at Weeks 52, 80 or 104.

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A. No Repigmentation* at Week 24 (n=55)

B. Limited Repigmentation† at Week 24 (n=138)

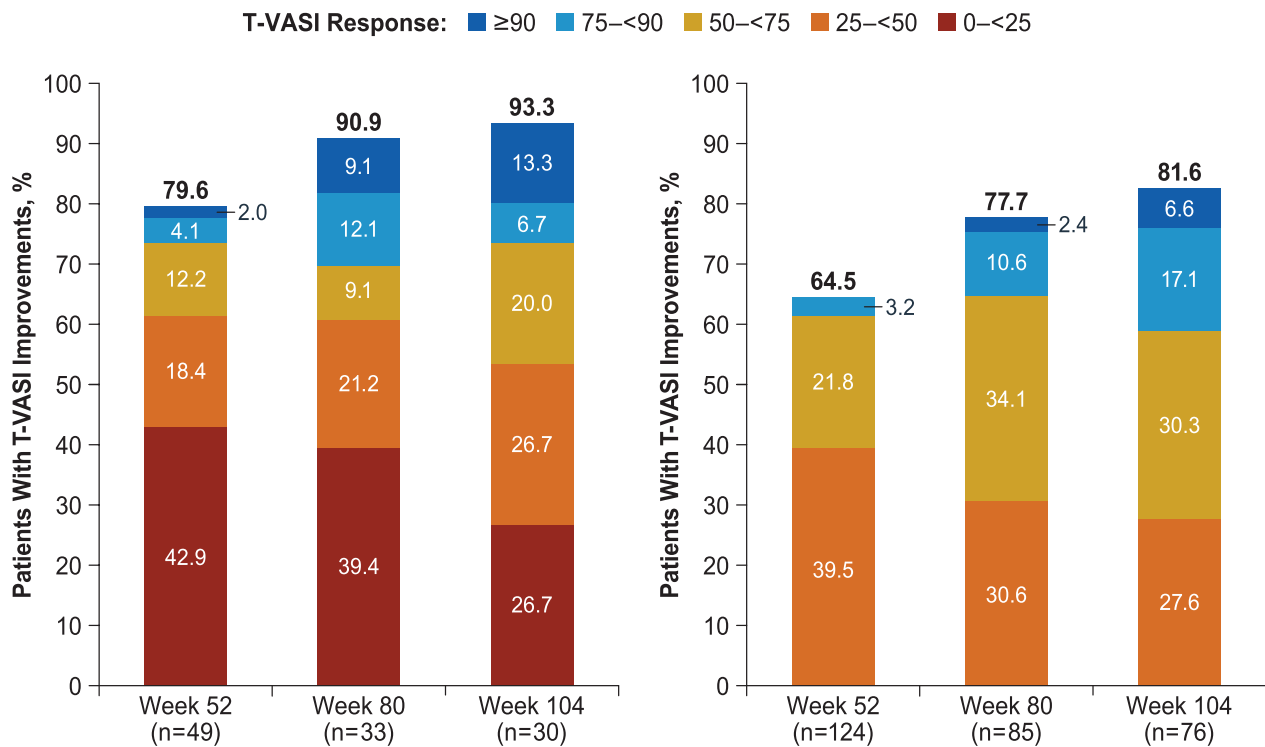


FIGURE 2 T-VASI response at Weeks 52, 80 and 104 among patients with continuous ruxolitinib cream treatment who had (a) no or (b) limited body repigmentation at Week 24. T-VASI, Total Vitiligo Area Scoring Index. *Patients with worsening or no improvement in T-VASI (i.e. $\leq 0\%$) at Week 24 and non-missing T-VASI values at Weeks 52, 80 or 104. †Patients with $>0\%$ –<25% improvement in T-VASI at Week 24 and non-missing T-VASI values at Weeks 52, 80 or 104.

Patients were randomized 2:1 to 1.5% ruxolitinib cream twice daily (BID) or vehicle for 24 weeks in TRuE-V1/TRuE-V2; all patients then applied 1.5% ruxolitinib cream BID for 28 additional weeks in an open-label extension.² Patients with $<90\%$ improvement in the facial Vitiligo Area Scoring Index ($<F\text{-VASI}90$) at Week 52 applied 1.5% ruxolitinib cream BID for an additional 52 weeks.³ Patients initially randomized to apply ruxolitinib cream who had $<25\%$ improvement from baseline in the facial or total Vitiligo Area Scoring Index (F-VASI or T-VASI) at Week 24 and had non-missing VASI assessments at Weeks 52, 80 and 104 (continuous BID ruxolitinib cream application) were included in this analysis. Shifts in F-VASI and T-VASI were assessed among these patients with no facial/body repigmentation or worsening depigmentation ($\leq 0\%$ improvement in F-VASI/T-VASI) and limited facial/total body repigmentation ($>0\%$ – $<25\%$ improvement in F-VASI/T-VASI) at Week 24.

Among 443 patients in the efficacy-evaluable population initially randomized to ruxolitinib cream, mean (SD) F-VASI and T-VASI at baseline were 0.92 (0.55) and 6.64 (2.04), respectively. Among patients with no or limited facial repigmentation at Week 24 ($n=127$), the percentage achieving F-VASI improvements increased from 71.7% at Week 52 ($n=113$) to 87.5% at Week 80 ($n=80$) and 90.1% at Week 104 ($n=71$), including 97.1% of patients with no repigmentation and 83.3% with limited repigmentation at Week

24 (Figure 1). Proportions of patients with no or limited repigmentation at Week 24 who achieved $\geq 75\%$ improvement from baseline in F-VASI (F-VASI75), a clinically meaningful threshold for facial repigmentation,^{9,10} increased throughout the study (Week 52, 13.3%; Week 80, 38.8%; Week 104, 54.9%).

Among patients with no or limited total body repigmentation at Week 24 ($n=193$), the percentage achieving T-VASI improvements increased from 68.8% at Week 52 ($n=173$) to 81.4% at Week 80 ($n=118$) and 84.9% at Week 104 ($n=106$), including 93.3% of patients with no repigmentation and 81.6% with limited repigmentation at Week 24 (Figure 2). The clinically meaningful threshold of $\geq 50\%$ improvement in T-VASI from baseline (T-VASI50) was achieved by 23.1%, 42.4% and 50.0% of patients at Weeks 52, 80 and 104, respectively.

In conclusion, $>80\%$ of patients with no or limited repigmentation at 6 months who continued to apply ruxolitinib cream over an additional 18 months achieved F-VASI or T-VASI improvements. Half of the patients achieved clinically meaningful F-VASI75 or T-VASI50 at 2 years. This analysis was limited by the number of patients with available data at later time points; patients with improvements may have been more likely to remain on treatment, resulting in attrition bias. Individualized decisions around prolonged treatment must weigh potential benefits alongside patient preferences, adherence and burden. These 2-year TRuE-V

results highlight the importance of prolonged treatment in patients with vitiligo, even when no or limited repigmentation is achieved after 6 months of treatment.

KEYWORDS

clinical trial, Janus kinase inhibitors, ruxolitinib cream, therapeutic studies, vitiligo

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FUNDING INFORMATION

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CONFLICT OF INTEREST STATEMENT

AW has served as principal investigator for AbbVie, Avita Medical, Incyte Corporation, MSD and Novartis; has served as an advisory board member for Incyte Corporation; has received research grants from Avita Medical and Lumenis; and has received devices from Humeca and PerfAction. MJG has served as a principal investigator for AbbVie, Acelyrin, Akros Pharma Inc., Alumis, Amgen, AnaptysBio, Apogee, Arcutis, Aristeia, Aslan, Attovia, Bausch Health, Boehringer Ingelheim International GmbH, Bristol Myers Squibb, Coherus Biosciences, Dermira, Eli Lilly, Galderma SA, GlaxoSmithKline, Incyte Corporation, Inmagene, JAMP, Janssen, Kyowa Kirin, LEO Pharma, MedImmune, Meiji, Merck, MoonLake, Nektar Therapeutics, Nimbus, Novartis, Oruka, Pfizer, Q32 Bio, Regeneron, Sanofi Genzyme, Sun Pharma, Takeda, Tarsus, UCB, Ventyx and Vyne; has been a consultant for AbbVie, Akros Pharma, Amgen, Apogee, Aslan, Bausch Health, Boehringer Ingelheim International GmbH, Eli Lilly, Janssen, Kyowa Kirin, Novartis Pharmaceuticals, Sanofi Genzyme, Sun Pharma and UCB; has been an advisory board member for AbbVie, Amgen, Apogee, Bausch Health, Boehringer Ingelheim International GmbH, Eli Lilly, Galderma SA, Incyte Corporation, Janssen, LEO Pharma, Novartis, Pfizer, Regeneron, Sanofi Genzyme, Sun Pharma, UCB and Union; and has been a paid speaker for AbbVie, Amgen, Bausch Health, Bristol Myers Squibb, Boehringer Ingelheim International GmbH, Eli Lilly, Galderma SA, Janssen, JAMP, LEO Pharma, L'Oreal, Novartis, Pfizer, Regeneron, Sanofi Genzyme, Sun Pharma and UCB. MS has received fees for consultancy and/or lectures and/or implementation of clinical studies for AbbVie, Affibody, Almirall, Amgen, Aristeia, AstraZeneca, Boehringer Ingelheim, Bristol Myers Squibb, Celgene, Dermira, Dr. August Wolff, Dr. Reddy's Laboratories, Eli Lilly, Galderma, Genentech, GlaxoSmithKline, Incyte Corporation, Janssen-Cilag, LEO Pharma, MedImmune, Menlo Therapeutics, MSD, Mundipharma, Medac, MoonLake, Novartis, Pfizer, Regeneron, Sanofi Genzyme and UCB Pharma. DR has served as a consultant, speaker or investigator for AbbVie, Abcuro, Almirall, AltruBio, Amgen, Arena, Astria, Boehringer Ingelheim, Bristol Myers Squibb, Celgene, Concert, CSL Behring, Dermavant

Sciences, Dermira, Dualitas, EMD Serono, Galderma, Incyte Corporation, Janssen, Kymera, Kyowa Kirin, Lilly, Merck, Nektar, Novartis, Pfizer, RAPT Therapeutics, Recludix, Regeneron Pharmaceuticals, Revolo Biotherapeutics, Sanofi, Sun Pharmaceuticals, UCB, Viela Bio and Zura Bio. AB has served as a speaker (received honoraria) for Almirall, Eli Lilly, Sanofi and UCB; has served as a scientific adviser (received honoraria) for AbbVie, Almirall, Alumis, Amgen, Anaptysbio, Apogee, Arcutis, Astria, Boehringer Ingelheim, Bristol Myers Squibb, Celltrion, Corvus, Dermavant, Eli Lilly, Galderma, GlaxoSmithKline, Immunovant, Incyte Corporation, IQVIA, Janssen, LEO Pharma, Lipidio, Merck, Novartis, Oruka, Paragon, Pfizer, Rani Therapeutics, Regeneron, Sanofi, Spherix Global Insights, Sun Pharma, Syncona, Takeda, UCB, Union and Zai Lab; has acted as a clinical study investigator (institution has received clinical study funds) for AbbVie, Acelyrin, Almirall, Alumis, Amgen, Arcutis, Boehringer Ingelheim, Bristol Myers Squibb, Dermavant, Eli Lilly, Galderma, Incyte Corporation, Janssen, LEO Pharma, Merck, Novartis, Pfizer, Regeneron, Sanofi, Sun Pharma, Takeda and UCB; and owns stock in Lipidio and Oruka. MSA has served as a principal investigator for Incyte Corporation, working on vitiligo clinical trials. JZ has served as an investigator for Almirall, Amgen, Bristol Myers Squibb, Celgene, Eli Lilly, Galderma, Incyte Corporation, Innovaderm, Pfizer, Regeneron, Sun Pharmaceuticals and Syneos Health. SW and DK are employees of Incyte Corporation. TP has received grants and/or honoraria from AbbVie, ACM Pharma, Almirall, Amgen, Astellas, Bristol Myers Squibb, Calypso, Celgene, Eli Lilly, Galderma, Genzyme/Sanofi, GlaxoSmithKline, Incyte Corporation, Janssen, LEO Pharma, Novartis, Pfizer, Sun Pharmaceuticals, Takeda, UCB and Vyne Therapeutics; is the cofounder of NIKAIA Pharmaceuticals; and has patents on WNT agonists and GSK3b antagonists for repigmentation of vitiligo and on the use of CXCR3B blockers in vitiligo. JEH has served as a consultant for AbbVie, Aclaris Therapeutics, BiologicsMD, EMD Serono, Genzyme/Sanofi, Janssen, Pfizer, Rheos Medicines, Sun Pharmaceuticals, TeVido BioDevices, The Expert Institute, 3rd Rock Ventures and Villaris Therapeutics; has served as an investigator for Aclaris Therapeutics, Celgene, Dermira, EMD Serono, Genzyme/Sanofi, Incyte Corporation, LEO Pharma, Pfizer, Rheos Medicines, Stiefel/GlaxoSmithKline, Sun Pharmaceuticals, TeVido BioDevices and Villaris Therapeutics; holds equity in Aldena Therapeutics, NIRA Biosciences, Rheos Medicines, TeVido BioDevices and Villaris Therapeutics; is a scientific founder of Aldena Therapeutics, NIRA Biosciences and Villaris Therapeutics; and has patents pending for IL-15 blockade for treatment of vitiligo, JAK inhibition with light therapy for vitiligo and CXCR3 antibody depletion for treatment of vitiligo.

DATA AVAILABILITY STATEMENT

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 data sets owned by

Incyte for the purpose of conducting legitimate scientific research. Researchers may request anonymized data sets 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 and 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>.

ETHICAL APPROVAL

The trial protocols were reviewed and approved by an institutional review board or ethics committee at participating centres. The trials were conducted in accordance with the Declaration of Helsinki and adhered to Good Clinical Practice guidelines and applicable country-specific laws and regulations.

ETHICS STATEMENT

All patients provided written informed consent.

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