Dermatol Ther (Heidelb) (2025) 15:381–394
https://doi.org/10.1007/s13555-025-01342-0

ORIGINAL RESEARCH

Real-World Effectiveness of Risankizumab in Patients with Moderate-to-Severe Psoriasis: Interim Analysis from the VALUE Global Prospective Post-marketing Observational Study at 25 Months

Diamant Thaçi · Mamitaro Ohtsuki · Julia-Tatjana Maul · Andrea Szegedi · Paula C. Luna · Charles W. Lynde · Ahmed M. Soliman · Hongwei Wang · Christian Kaufmann · Doug G. Ashley · Tshepiso Madihlaba · Simone Rubant · Kim A. Papp

Received: December 10, 2024 / Accepted: January 14, 2025 / Published online: February 4, 2025

ABSTRACT

Introduction: Risankizumab is approved for treating moderate-to-severe psoriasis. This interim analysis at 25 months evaluated the effectiveness of risankizumab compared with other approved biologics (OtherBios) among patients with moderate-to-severe psoriasis in the 37-month VALUE post-marketing observational study.

Methods: Patients diagnosed with psoriasis were enrolled in a 2:1 ratio to risankizumab or OtherBios, as prescribed by their physicians. A ≥ 90% improvement in Psoriasis Area Severity Index (PASI) 90 at months 4, 13, and 25 and the time to first treatment change at 25 months were evaluated. Additionally, PASI 100 and 75, static Physician Global Assessment (sPGA 0/1), Dermatology Life Quality Index (DLQI), and Treatment Satisfaction Questionnaire for Medication (TSQM) scores were evaluated. All patients treated with ≥ 1 dose of biological therapy with ≥ 1 post-baseline measurement were included in the analysis. Modified

Prior Presentations: Presented in part at the 33rd European Academy of Dermatology and Venereology Congress held September 25–28, 2024, in Amsterdam, the Netherlands, and at the 7th World Psoriasis & Psoriatic Arthritis Conference held June 27–29, 2024, in Stockholm, Sweden.

Supplementary Information The online version contains supplementary material available at https://doi.org/10.1007/s13555-025-01342-0.

D. Thaçi (✉)
Institute and Comprehensive Center for Inflammation Medicine, University of Lübeck, Ratzeburger Allee 160, Haus 50, Lübeck, Schleswig-Holstein, Germany
e-mail: Diamant.Thaci@uksh.de

M. Ohtsuki
Department of Dermatology, Jichi Medical University, Shimotsuke, Japan

J.-T. Maul
Department of Dermatology, University Hospital Zurich, Zurich, Switzerland

J.-T. Maul
Faculty of Medicine, University of Zurich, Zurich, Switzerland

A. Szegedi
Department of Dermatology, Faculty of Medicine, University of Debrecen, Debrecen, Hungary

P. C. Luna
Servicio de Dermatología, Hospital Alemán, Ciudad Autónoma de Buenos Aires, Argentina

C. W. Lynde
Lynde Institute for Dermatology & Lynderm Research Inc., Markham, ON, Canada

A. M. Soliman · H. Wang · C. Kaufmann · D. G. Ashley · T. Madihlaba · S. Rubant
AbbVie Inc., North Chicago, IL, USA

non-responder imputation was used to handle missing data, and propensity score matching accounted for imbalances between comparison groups.

***Results*:** Overall, 1765 patients received risankizumab and 874 received OtherBios. At baseline, the mean (SD) age of the overall population was 48.5 (14.7) years and mean (standard deviation [SD]) PASI scores were 15.0 (9.0) and 13.9 (8.8) in the risankizumab and OtherBios groups, respectively. At 25 months, 70.9% of those treated with risankizumab vs. 51.5% of those treated with OtherBios achieved PASI 90. The cumulative treatment change probability was 0.16 (95%, confidence interval [CI] 0.14, 0.18) in the risankizumab group and 0.29 (95% CI 0.26, 0.32) in the OtherBios group. At 25 months, a higher proportion of patients achieved PASI 100 (56.6% vs. 40.2%), PASI 75 (84.3% vs. 67.7%), sPGA 0/1 (82.6% vs. 66.2%), and DLQI 0/1 (70.0% vs. 52.9%) in the risankizumab vs. OtherBios group, respectively, and the change in mean TSQM global score was higher in the risankizumab group (86.0 vs. 79.4). All comparisons were nominally significant ($P<0.0001$). No new safety signals were identified.

***Conclusions*:** In this prospective study, risankizumab demonstrated higher effectiveness, longer drug survival, and better improvement of patient-reported outcomes at 25 months compared with OtherBios.

***Clinical Trials*:** ClinicalTrials.gov identifier: NCT03982394.

K. A. Papp
Alliance Clinical Trials and Probity Medical Research, Waterloo, ON, Canada

K. A. Papp
Division of Dermatology, Temerty Faculty of Medicine, University of Toronto, Toronto, ON, Canada

PLAIN LANGUAGE SUMMARY

The VALUE study is an ongoing 37-month post-marketing observational study that evaluates the effectiveness of risankizumab with other approved biologics (OtherBios) in treating moderate-to-severe plaque psoriasis in daily practice. Patients with a known diagnosis of psoriasis were included in the study by their treating physician in a 2:1 ratio to receive risankizumab or OtherBios. The treatment decision was made before and independent of study participation. The results presented here are from the interim analysis at 25 months. The study evaluated if patients achieved a 90% improvement in their skin clearance (Psoriasis Area Severity Index [PASI 90]) at months 4, 13, and 25 and if they stayed on the treatment before switching to a different treatment. The study also evaluated if patients achieved a complete (PASI 100) or 75% (PASI 75) improvement in skin clearance, assessed the overall skin condition (via the static Physician Global Assessment [sPGA 0/1]), and examined quality of life (via the Dermatology Quality of Life Index 0/1) and treatment satisfaction (via the Treatment Satisfaction Questionnaire for Medication scores). A total of 1,765 patients received risankizumab, while 874 received OtherBios. The average age was 48.5 years. At 25 months, 70.9% of the patients on risankizumab achieved PASI 90, compared to 51.5% on OtherBios, showing a clear advantage. The probability of a treatment change was lower for risankizumab patients. Additionally, 56.6% vs. 40.2% achieved PASI 100, 84.3% vs. 67.7% achieved PASI75, and 82.6% vs. 66.2% achieved sPGA0/1 with risankizumab vs. OtherBios, respectively. Quality of life and satisfaction scores were also higher for those on risankizumab. After accounting for differences between the two treatment groups, the results were better for risankizumab (nominal $P < 0.0001$). These findings show that risankizumab treatment is consistent with clinical trial results for risankizumab.

Keywords: IL 23 inhibitor; Risankizumab; Moderate-to-severe plaque psoriasis; Skin clearance; Quality of life; Real-world evidence

Key Summary Points

Why carry out this study?

Risankizumab is an interleukin (IL)–23 inhibitor approved for treating patients with moderate-to-severe plaque psoriasis.

VALUE is a 37-month post-marketing observational study that aims to evaluate the real-world effectiveness and durability of the response to risankizumab compared to other approved biologics (OtherBios, including guselkumab, adalimumab, ixekizumab, secukinumab, tildrakizumab, brodalumab, and ustekinumab) in patients with chronic moderate-to-severe plaque psoriasis.

What was learned from the study?

The results from the interim analysis at 25 months demonstrated that the patients treated with risankizumab achieved higher levels of skin clearance along with prolonged drug survival compared to patients treated with OtherBios.

The patients treated with risankizumab also reported higher patient-reported outcomes and treatment satisfaction than those treated with OtherBios.

These results demonstrate evidence of the real-world effectiveness of risankizumab treatment in regard to skin clearance, patient-reported quality of life, and treatment satisfaction outcomes compared to OtherBios beyond clinical trials.

The safety profiles of risankizumab and OtherBios were consistent with previous studies, and no new safety signals were identified.

INTRODUCTION

Moderate-to-severe plaque psoriasis is a chronic, immune-mediated inflammatory skin disease characterized by infiltrated, erythematous, scaly plaques resulting from abnormal keratinocyte proliferation and differentiation. Psoriasis considerably impacts the patient's quality of life (including physical, mental, and social aspects), which is also described as cumulative life course impairment (CLCI) [1]. Complete or almost-complete clearance of psoriatic plaques was achieved by different biologics in clinical trials. However, the durability of response in real-world clinical settings varies [2–5] and needs further investigation.

Risankizumab is an interleukin (IL)–23 inhibitor that selectively binds to the p19 subunit with high affinity, inhibiting the activation of pathogenic T helper 17 cells [6]. Clinical trials comparing risankizumab to ustekinumab (IL-12/IL-23 inhibitor) [7], adalimumab (tumor necrosis factor-α) [8], and secukinumab (IL-17A inhibitor) [9] demonstrate its superior efficacy over its comparators. Risankizumab showed consistently low rates of adverse events of interest along with high tolerability [10]. Although clinical trials have demonstrated the efficacy and safety of risankizumab, there is a need for real-world evidence to confirm these results in routine clinical practice as well as to assess the durability of its comparative effectiveness against other biologics (OtherBios) in real-world settings.

In this 37-month post-marketing observational VALUE study (NCT03982394), we evaluated the effectiveness, patient-reported outcomes, and safety among patients treated with risankizumab compared to OtherBios in a real-world setting. Herein, we present the results from the interim analysis from VALUE at 25 months.

MATERIAL AND METHODS

Study Design and Patients

This prospective, observational cohort study is being conducted in 21 countries, including Argentina, Australia, Austria, Canada, Colombia, Czech Republic, France, Germany, Hungary, Ireland, Italy, Japan, Mexico, the Netherlands, Poland, Romania, Saudi Arabia, Spain, Switzerland, United Arab Emirates, and the United

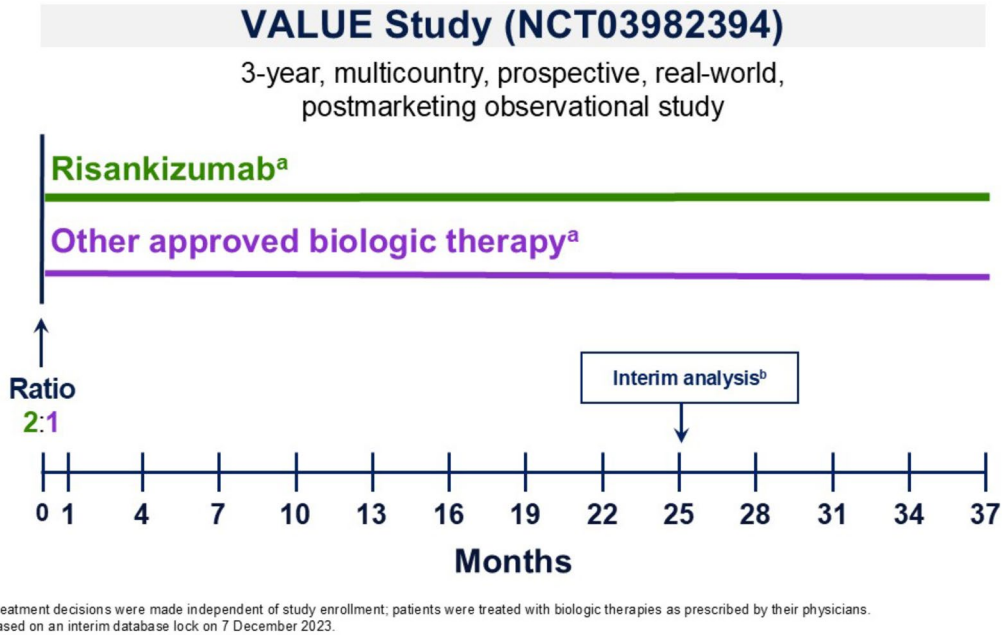

Fig. 1 VALUE study design

Kingdom. Patients (≥ 18 years) with a confirmed diagnosis of moderate-to-severe chronic plaque psoriasis who were treated by a physician (per local guidelines) with risankizumab or any OtherBios prior to this study were enrolled in a 2:1 ratio (Fig. 1). Treatment decisions were made independently by a treating physician prior to study enrollment. Patients participating in any interventional clinical trial were excluded. The study was conducted following applicable local guidelines and regulations. Approvals were obtained from local ethics committees of the relevant countries, and the patients provided written informed consent at study initiation. The study was conducted in accordance with the International Conference on Harmonisation, Good Clinical Practice Guidelines, and the Declaration of Helsinki.

Outcome Assessments

All patients who were treated with ≥ 1 dose of biologic treatment and had ≥ 1 post-baseline measurement were included in this interim analysis. Assessments were made according to the local clinical practice at baseline, month 4, and every 3 months thereafter for up to 37 months. The primary endpoints of the study included the proportion of patients who achieved Psoriasis Area Severity Index (PASI) 90 at month 4 and maintained it over 37 months and the time to first treatment change (including discontinuation, switching, dose escalation, and dosing-interval shortening). However, in this interim analysis, we analyzed data on the proportion of patients who reached PASI 90 at months 4, 13, and 25. Drug survival was assessed as the cumulative probability of a treatment change at month 25.

The key secondary endpoints evaluated in this interim analysis included the proportion of patients who achieved static Physician's Global Score (sPGA) 0/1 by visit, the proportion of patients who achieved PASI 75, PASI 90, and PASI 100 by visit, the change in absolute PASI from baseline, the proportion of patients who achieved Dermatology Quality of Life Index (DLQI) 0/1, the mean change in DLQI from baseline, and the Treatment Satisfaction Questionnaire for Medication (TSQM) version 1.4 global score by visit (assessed at months 0, 4, 13, and 25).

Adverse events were evaluated based on the reports provided by the physician to the sponsor. The interim safety dataset included all available information extending beyond month 25.

Statistical Analysis

The sample size estimate was based on the ability to provide at least 90% power to detect a 10% difference between the risankizumab and OtherBios groups in time to first treatment change rate at 37 months with a 2:1 patient allocation ratio. In the overall population (interim analysis dataset), the results were evaluated using the modified non-responder imputation method, which considered patients who switched or discontinued the initiated biologic due to ineffectiveness or intolerability to be treatment failures at all subsequent visits. To account for the imbalance between treatment groups, propensity score matching (PSM) with a 1:1 ratio using a greedy algorithm and exact matches for biologic-naïve and biologic-experienced status and other clinically important baseline characteristics were used.

t tests were used to compare continuous endpoints, while chi-squared tests were used for comparing categorical endpoints between groups. The time to first treatment change was analyzed using Kaplan–Meier estimates for each group. Group comparisons were performed in the overall and PSM populations to account for a baseline imbalance. Nominal *P* values were presented.

Adverse events were summarized as the number of events (E) per 100 patient-years (PY).

RESULTS

Baseline and Clinical Characteristics

The study enrolled 1776 and 881 patients treated with risankizumab and OtherBios, respectively (Supplementary Table S1). The number of patients evaluated at each time point is summarized in Supplementary Table S2. The most common biologics (used for treating ≥ 10% of patients) in the OtherBios group (Supplementary Table S3) included guselkumab (26.0%), adalimumab (17.2%), ixekizumab (15.7%), and secukinumab (13.8%).

The interim analysis dataset (overall population) included 1765 patients in the risankizumab group and 874 in the OtherBios group, with mean (SD) ages of 48.9 (14.7) and 47.7 (14.5) years, respectively; 37.1% were female in the risankizumab group vs. 43.3% in the OtherBios group. The mean PASI scores were 15.0 (9.0) vs. 13.9 (8.8) and the DLQI scores were 12.4 (7.6) vs. 12.7 (7.7) for the risankizumab group vs. the OtherBios group, respectively, and 49.3% of the risankizumab group were bio-experienced, vs. 37.1% in the OtherBios group (Table 1). Nearly half (50.3% and 49.0%) of the patients were diagnosed with psoriasis for ≥ 15 years in the risankizumab and OtherBios groups, respectively. The patients in the risankizumab group had a lower rate of psoriatic arthritis diagnosis at baseline compared to the OtherBios group (14.8% vs. 26.7%, respectively).

The baseline characteristics were generally comparable with the PSM analysis set (Supplementary Table S4).

By 25 months, 216 (12.2%) patients in the risankizumab group and 126 (14.4%) patients in the OtherBios group discontinued the study. The main reason for study discontinuation in the risankizumab group was being lost to follow-up (34.7%), whereas it was patient requests (34.1%) in the OtherBios group (Supplementary Table S5).

Achievement of the Primary Endpoint

Achievement of PASI 90

In the overall population, PASI 90 was achieved by 57.6%, 74.6%, and 70.9% of the risankizumab group and by 51.7%, 58.6%, and 51.5% of the OtherBios group (nominal $P < 0.0001$) at months 4, 13, and 25, respectively (Fig. 2A). The results were similar in the PSM population (Fig. 2B).

Drug Survival

The cumulative probability (95% CI) of a treatment change in the overall population at 25 months was 0.16 (0.14, 0.18) in the risankizumab group and 0.29 (0.26, 0.32) in the

Table 1 Baseline demographics and clinical characteristics

	Risankizumab *N* = 1765	**OtherBios** *N* = 874
Gender, *n* (%)		
Male	1109 (62.9)**	495 (56.7)
Female	654 (37.1)	378 (43.3)
Age, years (SD)	48.9 (14.7)*	47.7 (14.5)
Weight, kg (SD)	87.5 (21.9)*	85.4 (21.9)
Years since diagnosis, *n* (%)		
< 1 year	47 (2.7)	22 (2.5)
1 to ≤ 2 years	56 (3.2)	47 (5.4)
> 2 to ≤ 5 years	165 (9.4)	77 (8.8)
> 5 to ≤ 10 years	286 (16.3)	156 (17.9)
> 10 to ≤ 15 years	319 (18.2)	143 (16.4)
> 15 years	882 (50.3)	427 (49.0)
Missing	10	2
PASI, mean (SD)	15.0 (9.0)**	13.9 (8.8)
BSA, mean (SD)	22.3 (18.3)*	20.6 (17.1)
sPGA, mean (SD)	2.7 (0.8)*	2.6 (0.8)
DLQI, mean (SD)	12.4 (7.6)	12.7 (7.7)
Confirmed diagnosis of PsA, *n* (%)	259 (14.8)***	233 (26.7)
Pre-treatment, *n* (%)		
Bio-experienced	870 (49.3)***	324 (37.1)
Bio-naïve	895 (50.7)***	550 (62.9)
Any prior biologic use, *n* (%)	678 (38.4)	227 (26.0)

BSA body surface area, *DLQI* Dermatology Quality of Life Index, *PASI* Psoriasis Area and Severity Index, *PsA* psoriatic arthritis, *SD* standard deviation, *sPGA* static Physicians Global Assessment

*$P \leq 0.05$

**$P \leq .01$;

***$P \leq 0.0001$

Chi-squared tests were used for group comparisons

OtherBios group (Fig. 2C). The log-rank test revealed a significant difference between the groups (nominal $P<0.0001$). Similar results were noted for the PSM population (Fig. 2D).

Results for a treatment switch were similar to those observed for a treatment change. In the overall population, 10.1% of patients receiving risankizumab vs. 21.6% of patients receiving OtherBios experienced a treatment substance change by month 25 (nominal $P<0.0001$, Supplementary Table S6). The cumulative probability (95% CI) of a treatment substance change by month 25 was 0.09 (0.08, 0.11) for patients receiving risankizumab and 0.22 (0.19, 0.25) for patients receiving OtherBios. Results were similar in the PSM population (Fig. S1).

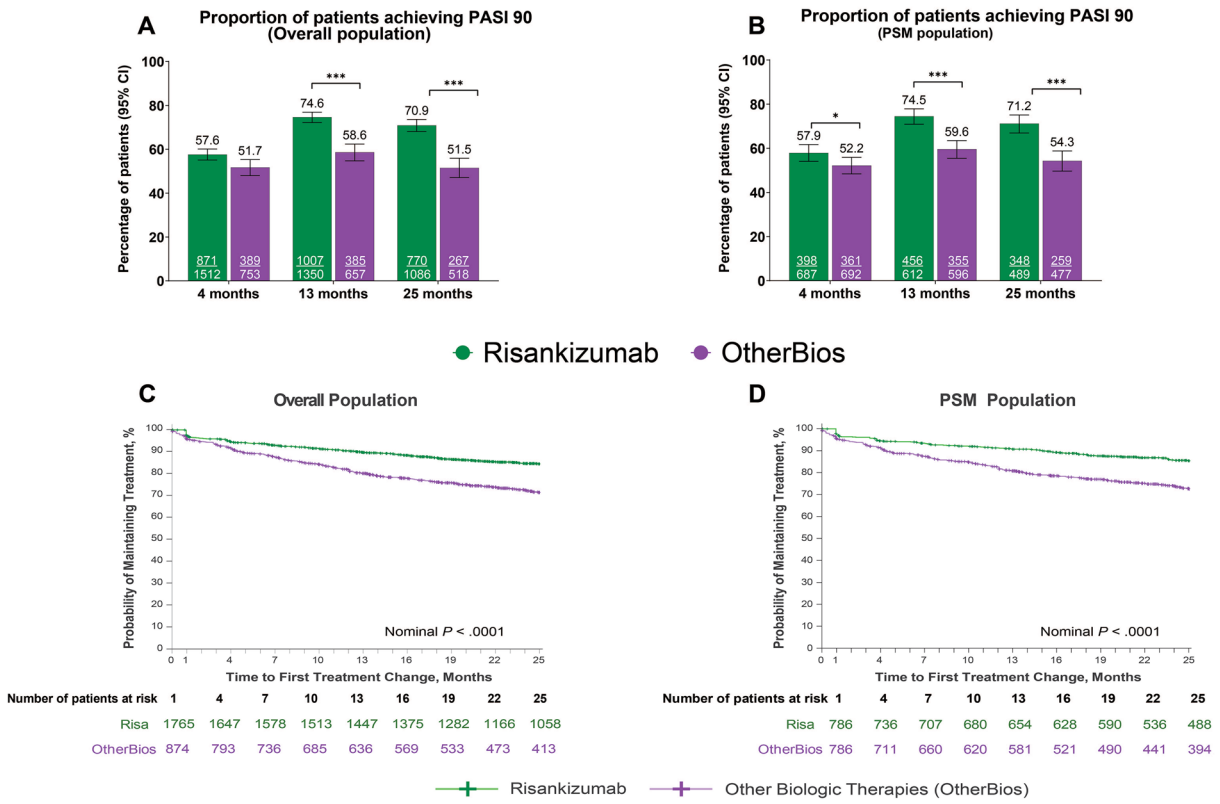

Fig. 2 Primary endpoints of the study. *CI* confidence interval, *PASI* Psoriasis Area Severity Index, *PSM* propensity score matching. **A** PASI 90 assessed by mNRI in the overall population. *mNRI* modified nonresponder imputation. **B** PASI 90 assessed by PSM. **C** Drug survival in the overall population. **D** Drug survival in the PSM population. *$P < 0.05$; ***, $P < 0.0001$

Achievement of Key Secondary Endpoints

Achievement of Skin Clearance

In the PSM population, at 25 months, 56.6% vs. 40.2% achieved PASI 100 and 84.3% vs. 67.7% achieved PASI 75 in the risankizumab vs. the OtherBios group, respectively (nominal $P < 0.0001$). The proportions of patients achieving PASI 100, 90, and 75 were higher in the risankizumab vs. the OtherBios group and remained stable over time (Fig. 3A–C). The mean PASI scores consistently decreased over time for both groups, but a higher decrease was noted in the risankizumab group compared to the OtherBios group (Fig. 3D). Patients in both treatment groups achieved reductions in their absolute PASI (≤ 5, ≤ 3, and ≤ 1) scores; however, the patients treated with risankizumab had a stable and greater proportion of PASI ≤ 1 compared to those treated with OtherBios over time (nominal $P < 0.05$, Supplementary Fig. S2).

At 25 months, the proportion of patients achieving sPGA 0/1 was also higher in the risankizumab vs. the OtherBios group (82.6% vs. 66.2%, nominal $P < 0.0001$, Fig. 3E).

Achievement of Patient-Reported Outcomes

In the overall population, the patients treated with risankizumab achieved greater improvements in DLQI and treatment satisfaction at month 25 (Supplementary Table S7). In the PSM population, 70.0% vs. 52.9% achieved DLQI 0/1 in the risankizumab vs. the OtherBios group (Fig. 4A). The mean DLQI scores at month 25

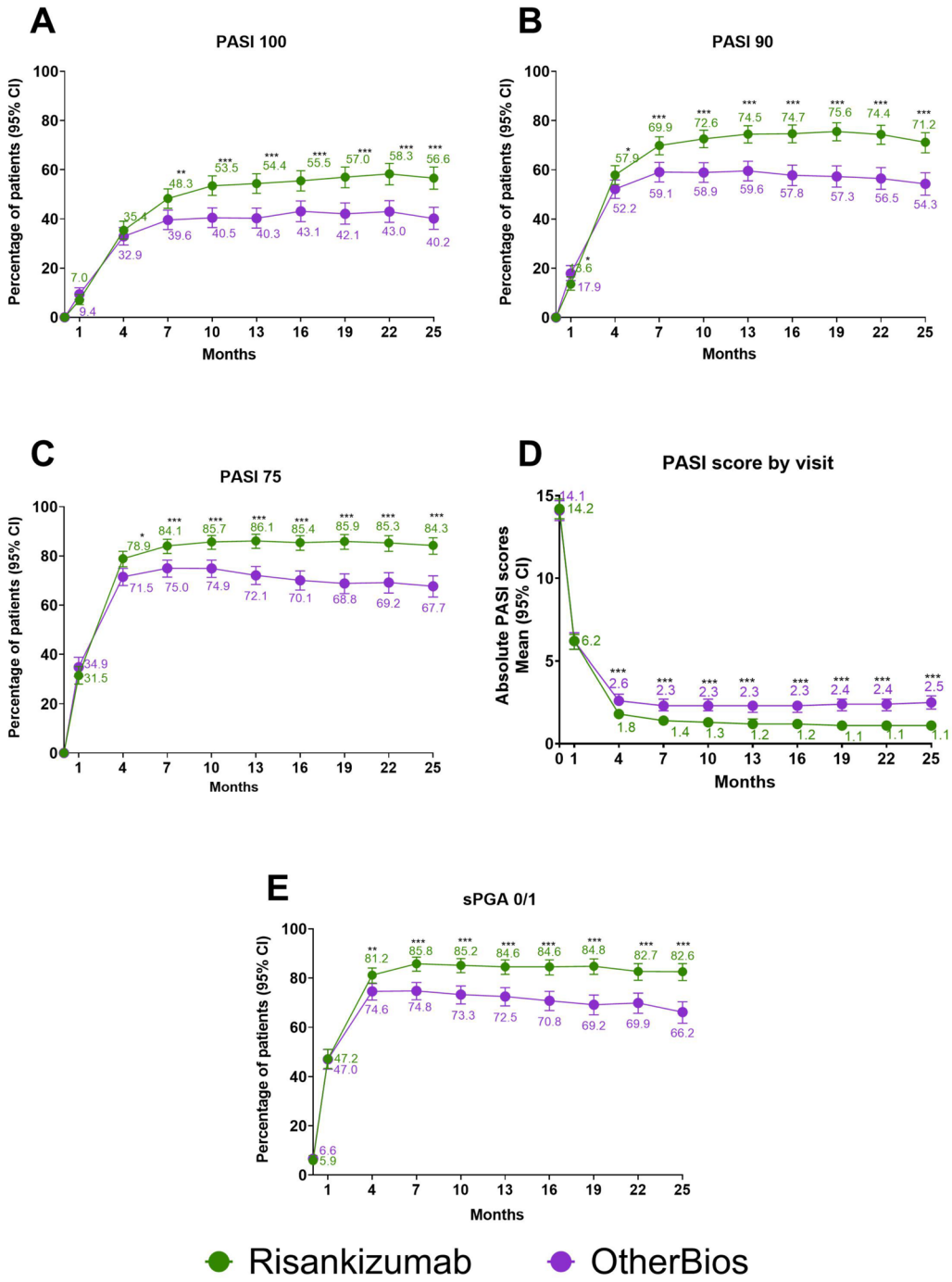

Fig. 3 Achievement of key secondary clinical endpoints by visit using propensity score matching. *CI* confidence interval, *PASI* Psoriasis Area Severity Index, *sPGA* static Physician Global Assessment. **A** Proportion of patients achieving PASI 100. **B** Proportion of patients achieving PASI 90. **C** Proportion of patients achieving PASI 75. **D** Change in PASI score by visit. **E** Proportion of patients achieving sPGA 0/1. $^{*}P \le 0.05$; $^{**}P \le 0.01$; $^{***}P \le 0.0001$

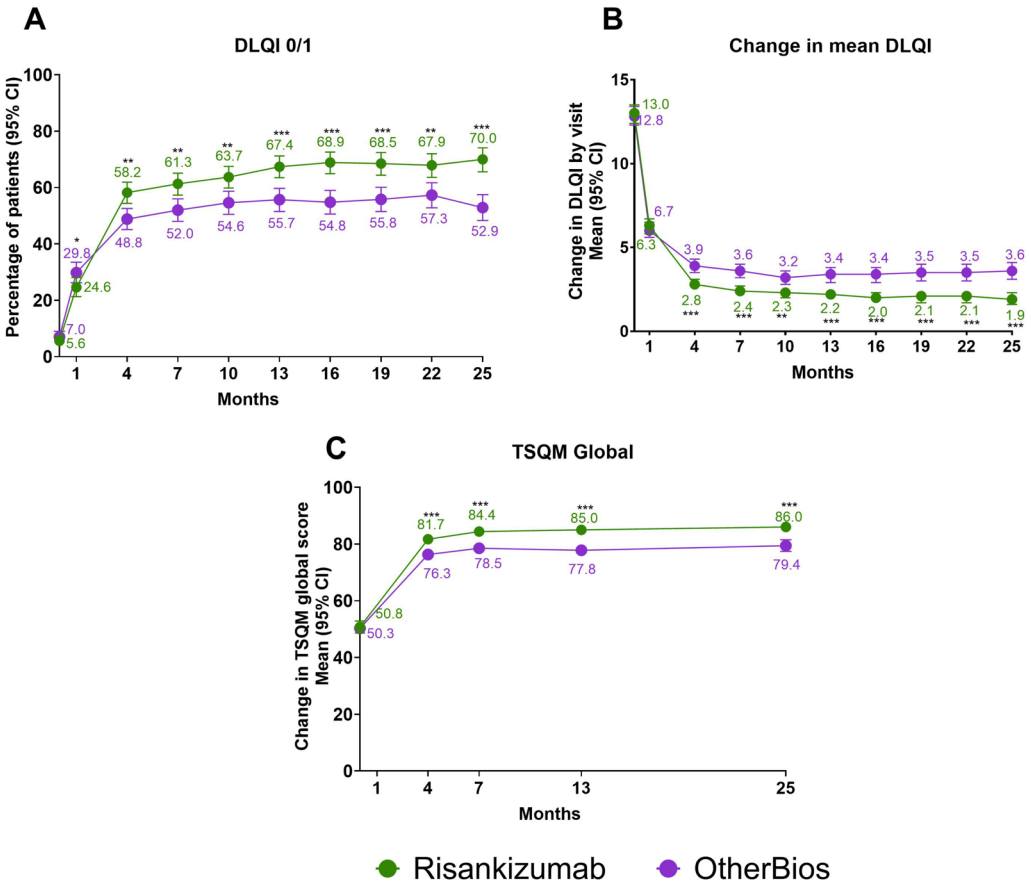

Fig. 4 Achievement of patient-reported outcomes using propensity score matching. **A** Proportion of patients achieving DLQI 0/1. **B** Mean change in DLQI. **C** Mean change in TSQM global scores. *CI* confidence interval, *DLQI* Dermatology Quality of Life Index, *TSQM* Treatment Satisfaction Questionnaire for Medication. $^{*}P \le 0.05$; $^{**}P \le 0.01$; $^{***}P \le 0.0001$

were 1.9 in the risankizumab group and 3.6 in the OtherBios group (Fig. 4B).

Patients in the risankizumab group achieved a higher mean change in TSQM global scores than those in the OtherBios group (86.0 vs. 79.4, Fig. 4C).

All comparisons were nominally significant, with $P<0.0001$.

Safety

Treatment with risankizumab did not show any new safety findings (Table 2). The rates of adverse events from all available data (57.5 vs. 71.7 E/100 PY), serious adverse events (6.2 vs. 7.9 E/100 PY), and infections (15.7 vs. 18.8 E/100 PY) were numerically lower in the risankizumab vs. the OtherBios group, respectively. Malignancy excluding non-melanoma skin cancer was rare, but its rate was numerically higher in the risankizumab vs. the OtherBios group (0.4 vs. 0.2 E/100PY). However, these rates are within the reference range for moderate-to-severe psoriasis reported in PSOLAR (0.5–0.8 E/100 PY) and the MarketScan® claims database (overall psoriasis population, 1.4 E/100 PY [11, 12].

DISCUSSION

Real-world studies provide valuable insights beyond those obtained from clinical trials. The

Table 2 Summary of adverse events per 100 PY

	Risankizumab (Total PY = 3926)		OtherBios (Total PY = 1863.8)	
	n (%)	E/100 PY	*n* (%)	E/100 PY
Any adverse event	2257 (100.0)	57.5	1337 (100.0)	71.7
Serious adverse events	245 (10.9)	6.2	148 (11.1)	7.9
Infections	615 (27.2)	15.7	350 (26.2)	18.8
Serious infections	37 (1.6)	0.9	21 (1.6)	1.1
Opportunistic infections	2 (0.1)	0.1	1 (0.1)	0.1
Candida sp.	17 (0.8)	0.4	14 (1.0)	0.8
Inflammatory bowel disease	0 (0.0)	0	2 (0.1)	0.1
NMSC	23 (1.0)	0.6	15 (1.1)	0.8
Malignant tumors excluding NMSC	16 (0.7)	0.4	4 (0.3)	0.2
MACE	22 (1.0)	0.6	10 (0.7)	0.5

E events, *PY* patient-years, *MACE* major adverse cardiac events, *NMSC* non-melanoma skin cancer, *OtherBios* other biological treatments

interim results from this large multicenter, prospective VALUE study provided robust real-world evidence of the effectiveness of risankizumab compared to OtherBios in treating patients with moderate-to-severe chronic plaque psoriasis in real-world settings.

Achieving complete skin clearance can improve a patient's quality of life. With newer biologics, the achievement of near-complete or complete skin clearance has become an attainable treatment goal for patients with psoriasis [13–15]. Our results showed that the patients treated with risankizumab reported greater and consistent improvement through month 25 for skin clearance (PASI 90, 100, and sPGA 0/1) than patients treated with OtherBios. These results are comparable to those observed in pivotal clinical trials (UltIMMA-1 and –2) and their long-term follow-up (LiIMMitless) [7, 16]. Notably, the baseline characteristics of the patients enrolled in VALUE were comparable to those enrolled in the pivotal clinical trials of risankizumab in age, gender, and mean body weight [7], and, despite the high prior biologic use among patients, the results demonstrate the robustness and consistent effectiveness and durability of risankizumab treatment in the real world.

These findings are further validated by other real-world studies that reported similar skin clearance outcomes among patients treated with risankizumab over 18 months [15]. Additionally, a network meta-analysis that compared the efficacy and safety of IL-17, IL-12/23, and IL-23 inhibitors in the short-term treatment of moderate-to-severe plaque psoriasis found that risankizumab had a relatively high efficacy and low risk [17]. Patients participating in the VALUE study were likely enrolled due to therapeutic switches without any washout. Lower baseline PASI scores were observed than those seen in clinical trials [7]. Matching clinical responses in real-world studies to clinical trials is challenging. However, risankizumab-treated patients in the VALUE study showed similar responses to the clinical trials, demonstrating robust effectiveness [7].

Patients receiving risankizumab were less likely to require treatment changes than patients receiving OtherBios. When treatment changes were required, these changes occurred later among patients receiving risankizumab vs.

OtherBios. These results further support the findings from another real-world and systematic review study that compared risankizumab with other commonly used IL-17, IL-12/23, and IL-23 inhibitors and found that risankizumab had a higher probability of drug survival compared to most IL-IL-17, IL-12/23, and IL-23 inhibitors [18, 19].

Though the patients enrolled in VALUE were previously treated, the DLQI scores were comparable to the pivotal trials [6], with baseline mean DLQI scores ≥ 12, indicating that psoriasis greatly affected the quality of life. Biologic treatments have been shown to significantly improve the quality of life among patients with psoriasis [20, 21]. Our results show that the patients treated with risankizumab improved their mean DLQI scores more than those treated with OtherBios, demonstrating the benefit of treating patients with risankizumab over OtherBios. These results were similar to those reported by another real-world study of risankizumab [15].

Prior research has demonstrated greater treatment satisfaction for moderate-to-severe psoriasis among biologic users than among nonbiologic users [22]. Our results show that the global scores for treatment satisfaction were higher with risankizumab compared to OtherBios.

The safety profile of risankizumab showed no new or unexpected signals and was comparable to the previously known safety profile of risankizumab [23].

The main strength of the VALUE study is its large multicenter, prospective, observational study design with an extended follow-up of 37 months in a real-world setting. The large sample size ensured that the study had the statistical power needed to detect meaningful effects and derive meaningful conclusions. Rigorous adjustment for baseline imbalances between treatment groups was done to ensure that the observed differences were likely due to the intervention. The results of this interim analysis are consistent with prior findings from the clinical trials [7] and demonstrate the robustness of the results. Some limitations of the study include its observational nature, with no randomization and potential unobserved confounders. The patient assessments did not follow a strict protocol but were based on routine clinical practice, the physician's judgment, and patient availability. This may have resulted in unequal durations of treatment and follow-ups of assessments at defined time intervals. The assessments were not centrally adjudicated, which may have resulted in reporting bias. The OtherBios group comprises several drug classes pooled into a single treatment group, and the small sample sizes of the groups might limit how meaningful a direct comparison with risankizumab is.

CONCLUSION

In conclusion, the interim results from the multicenter, observational VALUE study provide evidence supporting the benefit of treating patients with moderate-to-severe chronic plaque psoriasis with risankizumab rather than OtherBios in a real-world setting. The final data analysis will confirm these results in a real-world setting of patients with moderate-to-severe plaque psoriasis throughout the 37-month study period, which can help guide clinical practice.

Medical Writing/Editorial Assistance. Medical writing support was provided by Dalia Majumdar, PhD, and Susan Olalekan, PhD, and editorial support was provided by Angela T. Hadsell, BA, all of whom were employees of AbbVie.

Author Contributions. Diamant Thaçi, Simone Rubant, and Hongwei Wang contributed to the study's conception and design and the development of the methodology. Diamant Thaçi, Mamitaro Ohtsuki, Julia-Tatjana Maul, Andrea Szegedi, Paula C. Luna, Charles W. Lynde, and Kim A. Papp contributed to the acquisition of data (they acquired and managed patients, provided facilities, etc.). Diamant Thaçi, Mamitaro Ohtsuki, Julia-Tatjana Maul, Andrea Szegedi, Paula C. Luna, Charles W. Lynde, Ahmed M. Soliman, Hongwei Wang, Christian Kaufmann, Doug A. Ashley, Tshepiso Madihlaba, Simone Rubant, and Kim A. Papp

analyzed and interpreted the data (e.g., performed statistical analysis), commented on the drafts of the manuscript, and approved the final manuscript.

Funding. Risankizumab was developed in collaboration between AbbVie and Boehringer Ingelheim. AbbVie funded this research (NCT03982394) and participated in the design and conduct of the study, the analysis and interpretation of the data, and in the writing, review, and approval of this publication. All authors had access to relevant data and participated in the drafting, review, and approval of this manuscript. No honoraria or payments were made for authorship. AbbVie and the authors thank the participants, study sites, and investigators who participated in this clinical trial. Funding for the journal's Rapid Service Fee was provided by AbbVie.

Data Availability. AbbVie is committed to responsible data sharing regarding the clinical trials we sponsor. This includes access to anonymized, individual, and trial-level data (analysis datasets) as well as other information (e.g., protocols and clinical study reports) as long as the trials are not part of an ongoing or planned regulatory submission. This includes requests for clinical trial data for unlicensed products and indications. These clinical trial data can be requested by any qualified researchers who engage in rigorous, independent scientific research and will be provided following the review and approval of a research proposal and statistical analysis plan (SAP) and the execution of a data sharing agreement (DSA). Data requests can be submitted at any time after approval in the US and Europe and after the acceptance of this manuscript for publication. The data will be accessible for 12 months, with possible extensions considered. For more information on the process, or to submit a request, visit the following link: https://vivli.org/ourmember/abbvie/; after acceptance, select "Home."

Declarations

Conflict of Interest. Diamant Thaçi has been a consultant and an adviser and/or received speaking fees and/or grants and/or served as an investigator in clinical trials for the following companies: AbbVie, Almirall, Amgen, Boehringer Ingelheim, Bristol Myers Squibb, Celltrion, Eli Lilly, Galderma, Janssen-Cilag, LEO Pharma A/S, L'Oreal, Meiji, Newbridge, Novartis, Regeneron, Sanofi, Sun Pharma, Pfizer, Target RWE, UCB, and Vichy. He has received grants from AbbVie, LEO Pharma A/S, and Novartis. Mamitaro Ohtsuki has received honoraria or fees for serving on advisory boards or speakers' bureaus, fees for consulting, and grants for investigator activities from AbbVie, Amgen, BI, BMS, Celgene, Eisai, Janssen, Kyowa Kirin, LEO, Lilly, Maruho, Mitsubishi Tanabe Pharma, Novartis, Pfizer, Sun Pharma, Taiho, Torii, and UCB. Julia-Tatjana Maul has served as an adviser and/or received speaking fees and/or participated in clinical trials sponsored by AbbVie, Almirall, Amgen, BMS, Celgene, Eli Lilly, LEO Pharma, Janssen-Cilag, MSD, Novartis, Pfizer, Pierre Fabre, Roche, Sanofi, and UCB. Andrea Szegedi has received a research grant from AbbVie and lecture and/or consultant fees from Celgene, Eli Lilly, Janssen Pharmaceutical, LEO Pharma, AbbVie, Novartis, MSD, Pfizer, UCB, Galderma, and Sanofi. Paula C. Luna has received consulting fees, honoraria, or grant support or lecturing fees from Pierre Fabre Laboratory, Beiersdorf, Laboratoire La Roche Posay, Sanofi–Genzyme, AbbVie, Novartis, Janssen, Pfizer, Elli Lilly, Boehringer Ingelheim, Takeda, Bristol Myers Squibb, Galderma, and GlaxoSmithKline. Dr. Charles W. Lynde has been a speaker and/or consultant for AbbVie, Amgen, Aralez, Arcutis, Bausch Health, Bayer, Boehringer Ingelheim, Bristol Myers Squibb, Celgene, Cipher, Dermavant, Eli Lilly, Fresnius Kabi, Galderma, GSK, InCyte, Innovaderm, Intega Skin, Janssen, Kyowa Kirin, La Roche Posay, LEO Pharma, L'Oreal, Medexus, MedX, Merck, Novartis, P&G, Pediapharm, Pfizer, Regeneron, Roche, Sanofi Genzyme, Sandoz, Sentrex, SunPharma,TEVA, Tribute, UCB, Valeant, Viatris, Volo Health. He has been a principal investigator for AbbVie,

Acelyrin, Akros, Altius, Amgen, Aralez, Arcutis, Avillion, Bausch Health, Bayer, Boehringer Ingelheim, Bristol Myers Squibb, Celgene, Celltrion, Cipher, Concert, Dermavant, Devonian, Eli Lilly, Evelo, Galderma, GSK, InCyte, Innovaderm, Intega Skin, Janssen, Kyowa Kirin, La Roche Posay, LEO Pharma, L'Oreal, Medexus, MedX, Merck, MoonLake, Nimbus, Novartis, P&G, Pediapharm, Pfizer, Regeneron, Roche, Sanofi Genzyme, Sandoz, Sentrex, SunPharma, Takeda, TEVA, Tribute, UCB, Valeant, Viatris, Volo Health. Ahmed M. Soliman, Hongwei Wang, Christian Kaufmann, Doug A. Ashley, Tshepiso Madihlaba, and Simone Rubant are employees of AbbVie and may own stock, stock options, or patents. Kim A. Papp has received honoraria and/or grants from and is a consultant, investigator, or a scientific officer for AbbVie, Acelyrin, Akros, Alumis, Amgen, Arcutis, Bausch Health/Valeant, Boehringer Ingelheim, Bristol Myers Squibb, Can-Fite Biopharma, Celltrion, Concert Pharmaceuticals, Dermavant, Dermira, DiCE Pharmaceuticals, DiCE Therapeutics, Eli Lilly and Company, Evelo Biosciences, Forbion, Galderma, Horizon Therapeutics, Incyte Corporation, Janssen, Kymab, Kyowa Hakko Kirin, LEO Pharma, Meiji Seika Pharma, Mitsubishi Pharma, Nimbus Therapeutics, Novartis, Pfizer, Reistone, Sanofi-Aventis/Genzyme, Sandoz, Sun Pharma, Takeda, Tarsus Pharmaceuticals, UCB Pharma, and Zai Lab. Orcid: 0000–0001-9557–3642.

Ethical Approval. This post-marketing observational study was conducted following the protocol and applicable local guidelines and regulations. Approvals were obtained from local ethics committees of the relevant countries, and the patients provided written informed consent at study initiation. The study was conducted in accordance with the International Conference on Harmonisation, Good Clinical Practice Guidelines, and the Declaration of Helsinki.

REFERENCES

1. Kimball A, Gieler U, Linder D, Sampogna F, Warren R, Augustin M. Psoriasis: is the impairment to a patient's life cumulative? J Eur Acad Dermatol Venereol. 2010;24:989–1004.

2. Muijen MEV, Thomas SE, Groenewoud HMM, Otero ME, Ossenkoppele PM, Njoo MD, et al. Direct comparison of real-world effectiveness of biologics for psoriasis using absolute and relative psoriasis area and severity index scores in a prospective multicentre cohort. Acta Derm-Venereol. 2022;102:adv00712.

3. Maul JT, Augustin M, Sorbe C, Conrad C, Anzengruber F, Mrowietz U, et al. Association of sex and systemic therapy treatment outcomes in psoriasis: a two-country, multicentre, prospective, noninterventional registry study. Br J Dermatol. 2021;185:1160–8.

4. Armstrong AW, Soliman AM, Betts KA, Wang Y, Gao Y, Stakias V, et al. Long-term benefit-risk profiles of treatments for moderate-to-severe plaque psoriasis: a network meta-analysis. Dermatol Ther. 2021;12:167–84.

5. Sbidian E, Chaimani A, Guelimi R, Garcia-Doval I, Hua C, Hughes C, et al. Systemic pharmacological treatments for chronic plaque psoriasis: a network meta-analysis. Cochrane Database Syst Rev. 2023;2023:CD011535.

6. Singh S, Kroe-Barrett RR, Canada KA, Zhu X, Sepulveda E, Wu H, et al. Selective targeting of the IL23 pathway: generation and characterization of a novel high-affinity humanized anti-IL23A antibody. MAbs. 2015;7:778–91.

7. Gordon KB, Strober B, Lebwohl M, Augustin M, Blauvelt A, Poulin Y, et al. Efficacy and safety of

risankizumab in moderate-to-severe plaque psoriasis (UltIMMa-1 and UltIMMa-2): results from two double-blind, randomised, placebo-controlled and ustekinumab-controlled phase 3 trials. Lancet. 2018;392:650–61.

8. Reich K, Gooderham M, Thaci D, Crowley JJ, Ryan C, Krueger JG, et al. Risankizumab compared with adalimumab in patients with moderate-to-severe plaque psoriasis (IMMvent): a randomised, double-blind, active-comparator-controlled phase 3 trial. Lancet. 2019;394:576–86.

9. Warren RB, Blauvelt A, Poulin Y, Beeck S, Kelly M, Wu T, et al. Efficacy and safety of risankizumab vs. secukinumab in patients with moderate-to-severe plaque psoriasis (IMMerge): results from a phase III, randomized, open-label, efficacy-assessor-blinded clinical trial. Br J Dermatol. 2021;184:50–9.

10. Gordon KB, Lebwohl M, Papp KA, Bachelez H, Wu JJ, Langley RG, et al. Long-term safety of risankizumab from 17 clinical trials in patients with moderate-to-severe plaque psoriasis. Br J Dermatol. 2022;186:466–75.

11. Papp KA, Langholff W. Safety surveillance for ustekinumab and other psoriasis treatments from the Psoriasis Longitudinal Assessment and Registry (PSOLAR) Errata. J Drugs Dermatol. 2020;19:571–2.

12. Kimball AB, Schenfeld J, Accortt NA, Anthony MS, Rothman KJ, Pariser D. Cohort study of malignancies and hospitalized infectious events in treated and untreated patients with psoriasis and a general population in the United States. Br J Dermatol. 2015;173:1183–90.

13. Elewski BE, Puig L, Mordin M, Gilloteau I, Sherif B, Fox T, et al. Psoriasis patients with Psoriasis Area and Severity Index (PASI) 90 response achieve greater health-related quality-of-life improvements than those with PASI 75–89 response: results from two phase 3 studies of secukinumab. J Dermatol Treat. 2017;28:492–9.

14. Augustin M, Gottlieb AB, Lebwohl M, Pinter A, Warren RB, Puig L, et al. Complete skin clearance is associated with the greatest benefits to health-related quality of life and perceived symptoms for patients with psoriasis. Dermatol Ther. 2024;14:2841–57.

15. Pinter A, Soliman AM, Pivneva I, Ghanbariamin R, Yang M, Truong B, et al. Real-world long-term effectiveness of risankizumab among patients with moderate-to-severe psoriasis: analysis from an international medical chart review (RAPID) study. Dermatol Ther. 2024;14:1259–71.

16. Papp KA, Blauvelt A, Puig L, Ohtsuki M, Beissert S, Gooderham M, et al. Long-term safety and efficacy of risankizumab for the treatment of moderate-to-severe plaque psoriasis: Interim analysis of the LIMMitless open-label extension trial up to 5 years of follow-up. J Am Acad Dermatol. 2023;89:1149–58.

17. Bai F, Li GG, Liu Q, Niu X, Li R, Ma H. Short-term efficacy and safety of IL-17, IL-12/23, and IL-23 inhibitors brodalumab, secukinumab, ixekizumab, ustekinumab, guselkumab, tildrakizumab, and risankizumab for the treatment of moderate to severe plaque psoriasis: a systematic review and network meta-analysis of randomized controlled trials. J Immunol Res. 2019;2019:2546161.

18. Gargiulo L, Ibba L, Malagoli P, Balato A, Bardazzi F, Burlando M, et al. Drug survival of IL-12/23, IL-17 and IL-23 inhibitors for moderate-to-severe plaque psoriasis: a retrospective multicenter real-world experience on 5932 treatment courses—IL PSO (Italian landscape psoriasis). Front Immunol. 2024;14:1341708.

19. Thomas SE, Barenbrug L, Hannink G, Seyger MMB, de Jong EMGJ, van den Reek JMPA. Drug survival of IL-17 and IL-23 inhibitors for psoriasis: a systematic review and meta-analysis. Drugs. 2024;84:565–78.

20. de Ruiter CC, Rustemeyer T. Biologics can significantly improve Dermatology Life Quality Index (DLQI) in psoriatic patients: a systematic review. Psoriasis Targets Ther. 2022;12:99–112.

21. Raam L, Hartmane I, Valiukevičienė S, Karamova AE, Telegdy E, Botev I, et al. Disease severity, treatment patterns, and quality of life in patients with moderate-to-severe psoriasis routinely managed with systemic treatment: results of the CRYSTAL observational study in Central and Eastern European countries. Front Immunol. 2024;15:1410540.

22. Ighani A, Yu AM, Sandhu VK, Barankin B, Manolson MF. Satisfaction and awareness of systemic psoriasis treatments: a national survey comparing biologic and nonbiologic users. J Cutan Med Surg. 2019;23:148–56.

23. Gordon KB, Blauvelt A, Bachelez H, Coates LC, den Bosch FEV, Kaplan B, et al. Long-term safety of risankizumab in patients with psoriatic disease: a comprehensive analysis from clinical trials. Dermatol Ther. 2024;14:2523–38.