RHEUMATOLOGY

Rheumatology 2023;62:629–637
https://doi.org/10.1093/rheumatology/keac342
Advance access publication 8 July 2022

Original article

Risankizumab improved health-related quality of life, fatigue, pain and work productivity in psoriatic arthritis: results of KEEPsAKE 1

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Abstract

Objectives. PsA is a heterogeneous disease that impacts many aspects of social and mental life, including quality of life. Risankizumab, an antagonist specific for IL-23, is currently under investigation for the treatment of adults with active PsA. This study evaluated the impact of risankizumab *vs* placebo on health-related quality of life (HRQoL) and other patient-reported outcomes (PROs) among patients with active PsA and inadequate response or intolerance to conventional synthetic DMARD (csDMARD-IR) in the KEEPsAKE 1 trial.

Methods. Adult patients with active PsA ($n = 964$) were randomized (1:1) to receive risankizumab 150 mg or placebo. PROs assessed included the 36-Item Short-Form Health Survey (SF-36, v2), Functional Assessment of Chronic Illness Therapy–Fatigue (FACIT-Fatigue), EuroQoL-5 Dimension-5 Level (EQ-5D-5L), Patient's Assessment of Pain, Patient's Global Assessment (PtGA) of Disease Activity, and Work Productivity and Activity Impairment–PsA (WPAI-PsA) questionnaire. Least squares (LS) mean change from baseline at week 24 was compared between risankizumab and placebo.

Results. At week 24, differences between groups were observed using LS mean changes from baseline in SF-36 physical component summary and mental component summary; FACIT-Fatigue; EQ-5D-5L; Patient's Assessment of Pain; PtGA; all eight SF-36 domains (all nominal $P < 0.001$); and the WPAI-PsA domains of impairment while working (presenteeism), overall work impairment and activity impairment (all nominal $P < 0.01$).

Conclusion. Risankizumab treatment resulted in greater improvements in HRQoL, fatigue, pain and work productivity in patients with active PsA who have csDMARD-IR, when compared with placebo.

Trial registration. ClinicalTrials.gov, https://clinicaltrials.gov, NCT03675308

Key words: outcome measures, spondyloarthropathies (including psoriatic arthritis), quality of life, biological therapies, DMARDs, patient attitude to health

CLINICAL SCIENCE

Rheumatology key messages

- Our study evaluated the impact of risankizumab *vs* placebo on health-related quality of life.
- Risankizumab *vs* placebo treatment resulted in greater improvements in fatigue and pain.
- Risankizumab treated patients also reported greater improvements *vs* placebo in work productivity.

Introduction

PsA is a chronic systemic inflammatory disease characterized by the association between arthritis and psoriasis [1]. Insufficient treatment of patients with PsA can lead to persistent inflammation, progressive joint damage and disability [2]. Patients with PsA have an increased risk of comorbidities; those with more severe disease and/or a higher number of comorbidities reported worse impacts

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Submitted 4 November 2021; accepted 6 May 2022

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of their disease on functioning, work disability and quality of life (QoL) [3]. Patients with PsA have lower income, long-term work disability and higher societal costs, including healthcare costs, particularly around the time of diagnosis [4, 5]. PsA negatively affects multiple aspects of life, including reduced physical and psychosocial health-related QoL (HRQoL) [3, 6–8].

An important outcome of treating patients with PsA is to maximize long-term HRQoL through symptom control, prevention of structural damage, normalization of physical function and social participation, and abrogation of inflammation. Current treatments for PsA include conventional synthetic DMARDs (csDMARDs); biologic therapies like TNF, IL-17, and IL-12/23 inhibitors; and, more recently, targeted therapies such as phosphodiesterase-4 inhibitors, Janus kinase (JAK) inhibitors [9, 10] and the IL-23 inhibitor guselkumab [11]. Despite the beneficial results achieved with currently available therapies, a number of patients do not achieve reduced disease activity and clinical remission [12–14]. Thus, there remains a clear medical need for additional therapeutic options in PsA for patients with inadequate response to or intolerance of currently available therapies.

Risankizumab is an antagonist specific for IL-23 that has been implicated in the pathophysiology of a specific group of immune-mediated inflammatory diseases [15]. In clinical trials of patients with moderate to severe plaque psoriasis, risankizumab has proven effective in significantly reducing symptoms and improving HRQoL when compared with ustekinumab and placebo [16–18]. Additionally, risankizumab was shown to effectively reduce symptoms of PsA in patients with active PsA who had an inadequate response to biologics and/or csDMARDs (csDMARD-IR) [19–21]. Since PsA significantly impacts HRQoL, we examined the effect of risankizumab *vs* placebo on HRQoL, fatigue, pain and work productivity in csDMARD-IR patients with active PsA.

Methods

Study design

KEEPsAKE 1 (NCT03675308) is a phase 3, randomized, double-blind, placebo-controlled, parallel-group, global, multicentre study (see Supplementary Materials, available at *Rheumatology* online). The study compared risankizumab with placebo in patients with active PsA who have an inadequate response or intolerance to at least one csDMARD. Patients were randomized (1:1) to receive blinded risankizumab 150 mg or placebo by subcutaneous injection at weeks 0, 4 and 16. Full details on study design were previously reported [19, 20].

Patients

Patients aged 18 years and older with a clinical diagnosis of PsA (with symptom onset at least 6 months prior to the screening visit and fulfilment of the classification criteria for PsA [CASPAR] at the screening visit) were included. Active arthritis was defined as $\geq$5 tender joints (based on 68 joint counts) and $\geq$5 swollen joints (based on 66 joint counts) at both the screening visit and baseline. Additional eligibility requirements included having active plaque psoriasis (with at least 1 psoriatic plaque of $\geq$2 cm in diameter) or nail psoriasis; no prior exposure to biologics including risankizumab; and inadequate response (lack of efficacy after a minimum 12-week duration of therapy), intolerance to or contraindication for csDMARDs. Further details of the patient population have been provided in a separate publication [19, 20].

Measures

This analysis evaluated several patient-reported outcomes (PROs) across a wide range of HRQoL measures as additional endpoints in the KEEPsAKE 1 trial. The PROs included in this study were the 36-Item Short-Form Health Survey (SF-36, v2), Functional Assessment of Chronic Illness Therapy–Fatigue (FACIT-Fatigue), EuroQoL-5 Dimension-5 Level (EQ-5D-5L), Patient's Assessment of Pain on a visual analogue scale (VAS), Patient's Global Assessment (PtGA) of Disease Activity on a VAS, and Work Productivity and Activity Impairment–PsA (WPAI-PsA).

SF-36 is a 36-item survey of patient health consisting of two composite scores (physical component summary [PCS] and mental component summary [MCS]) and eight subdomain scores: physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional and mental health. SF-36 PCS and MCS were norm-based, with a mean value of 50 and standard deviation of 10; SF-36 domains were scored from 0 to 100, with higher scores indicating better HRQoL and a more favourable health state [22–24].

FACIT-Fatigue is a 13-item questionnaire with answers on a five-point Likert scale; the total score ranges from 0 to 52. This instrument evaluates fatigue and includes items such as tiredness, weakness, listlessness, lack of energy and the impact of these feelings on daily functioning (e.g. sleeping and social activities). A higher score indicates less fatigue [25].

EQ-5D-5L is a health state utility instrument that evaluates preference for health status (utility). The five items in the EQ-5D-5L comprise five dimensions (mobility, self-care, usual activities, pain/discomfort and anxiety/depression) that are rated on five levels of severity and converted into a utility score $\leq$1, with lower scores indicating greater impairment [26]. Patients also rate their perception of their overall health on a separate VAS [27].

Patient's Assessment of Pain (VAS) is a self-reported measure to assess pain, ranging from 0 (no pain) to 100 (severe pain), during the previous 24 h [28]. PtGA evaluates the patient's overall functionality, considers disease activity within the previous 24 h, and is scored on a 100-mm horizontal scale, with 0 being very well and 100 being very poorly [29, 30].

WPAI-PsA is an instrument that measures impairments in work and activities with four subscales (absenteeism, presenteeism, overall work impairment and activity impairment) scored from 0% to 100%, with higher

percentages indicating greater impairment and less productivity. It comprises six questions that assess the effect of PsA on the patient's ability to work and perform regular activities during the previous 7 days [31, 32].

Patient's Assessment of Pain and PtGA were evaluated at baseline and at weeks 4, 8, 12, 16 and 24. SF-36, EQ-5D-5L, FACIT-Fatigue and WPAI-PsA were assessed at baseline and at weeks 12 and 24. The normative value was ≤20 points for Patient's Assessment of Pain and PtGA, ≥50 points for SF-36 PCS and MCS scores, ≥0.915 for EQ-5D-5L index score and ≥40.1 points for FACIT-Fatigue [33].

Statistical analysis

Demographics and baseline characteristics were summarized. For categorical variables, frequencies and percentages were summarized. For continuous variables, the mean and standard deviation were reported. Non-responder imputation incorporating multiple imputation was implemented to handle missing data due to COVID-19 (NRI-C). Least squares mean changes from baseline at week 24 were compared between the risankizumab treatment group *vs* placebo, using mixed-effects repeated measures modeling (MMRM). For the MMRM analysis, data collected after initiation of concomitant medications for PsA that could meaningfully impact efficacy assessment or initiation of rescue therapy were excluded. The mixed model included the categorical fixed effects of treatment; visit and treatment-by-visit interaction; stratification factors including current use of csDMARD (0 *vs* ≥1), presence of dactylitis (yes/no), presence of enthesitis (yes/no) and extent of psoriasis (≥3% BSA or <3% BSA) at baseline; and the continuous fixed covariate of baseline measurement. An unstructured variance covariance matrix was used. *P*-values of all measures were reported as nominal.

Results

Demographics and clinical characteristics at baseline

A total of 964 patients were evaluated in this study, with 483 randomized to risankizumab and 481 to placebo (Supplementary Fig. S1, available at *Rheumatology* online). Of the total population of patients, 50.4% ($n = 486$) were male, the mean age was 51.3 years (S.D. = 12.2), and the mean duration of PsA was 7.1 years (S.D. = 7.4). Baseline characteristics were similar between treatment groups (Table 1).

At baseline, a majority of patients ($n = 649$, 67.3%) had received only one prior csDMARD (risankizumab: $n = 338$, 70.0%; placebo: $n = 311$, 64.7%) and 60.2% ($n = 580$) of all patients were receiving concomitant therapy with methotrexate alone (risankizumab: $n = 294$, 60.9%; placebo: $n = 286$, 59.5%; Table 1).

Overall, mean PRO scores at baseline were similar in the risankizumab and placebo groups (Table 2). Based on normative values of the respective outcome measures, the mean PRO scores at baseline demonstrate that disease was having a substantial impact on HRQoL.

Least squares mean change from baseline

Fatigue, pain, general health status (EQ-5D-5L) and disease activity (PtGA)

At week 24, risankizumab treatment resulted in significant improvements compared with placebo in multiple PROs. Specifically, the mean change in FACIT-Fatigue from baseline to week 24 in patients treated with risankizumab was greater than the mean change in patients receiving placebo, which resulted in a difference of 2.6 between groups (95% CI: 1.5, 3.7; nominal $P < 0.001$; Table 3). Differences between the risankizumab and placebo groups were also observed in EQ-5D-5L index and VAS scores. A 0.07-point difference (95% CI: 0.05, 0.09; nominal $P < 0.001$) and a 5.8-point difference (95% CI: 3.1, 8.4; nominal $P < 0.001$) were observed for the EQ-5D-5L index and VAS scores, respectively. Patients treated with risankizumab reported greater improvement in pain compared with those receiving placebo, resulting in a difference between groups of −10.7 (95% CI: −13.7, −7.8; nominal $P < 0.001$). A difference between groups was also noted in disease activity in which an −11.1-point difference (95% CI: −14.1, −8.1; nominal $P < 0.001$) in PtGA was observed.

SF-36 component and domain scores

Figure 1 illustrates between-group differences in least squares mean change from baseline to week 24 for the SF-36 component summary and domain scores. Risankizumab treatment resulted in improvement in SF-36 PCS, MCS, and all eight domain scores compared with placebo.

WPAI-PsA

Patients treated with risankizumab reported greater improvement in activity impairment and presenteeism compared with those receiving placebo, resulting in differences between groups (nominal $P < 0.001$; Fig. 2). A −7.7-point difference (95% CI: −10.7, −4.7; nominal $P < 0.001$), a −10.1-point difference (95% CI: −14.3, −5.9; nominal $P < 0.001$), and a −8.1-point difference (95% CI: −13.1, −3.1; nominal $P < 0.01$) were observed for the activity impairment, presenteeism scores and overall work impairment, respectively. There was no significant difference between groups in absenteeism ($P = 0.60$).

Discussion

Results from KEEPsAKE 1, a study in patients with PsA with inadequate response or intolerance to csDMARDs, demonstrated that risankizumab improved PROs at week 24 compared with placebo. The PROs assessed in this study encompassed several areas that substantially impact HRQoL, fatigue, pain and work productivity. These

Table 1 Baseline demographics and clinical characteristics

Demographics	Total ($n = 964$)	Risankizumab 150 mg ($n = 483$)	Placebo ($n = 481$)
Male, *n* (%)	486 (50.4)	252 (52.2)	234 (48.6)
Age, mean (S.D.), years	51.3 (12.2)	51.3 (12.2)	51.2 (12.1)
White race, *n* (%)	905 (93.9)	454 (94.0)	451 (93.8)
Duration of PsA, mean (S.D.), years	7.1 (7.4)	7.1 (7.0)	7.1 (7.7)
Tobacco use, *n* (%)[a]			
Current	184 (19.1)	89 (18.4)	95 (19.8)
Former	177 (18.4)	91 (18.8)	86 (17.9)
Never	602 (62.5)	303 (62.7)	299 (62.3)
Unknown	1	0	1
Alcohol use, *n* (%)[a]			
Current	394 (41.2)	197 (41.2)	197 (41.1)
Former	73 (7.6)	44 (9.2)	29 (6.1)
Never	490 (51.2)	237 (49.6)	253 (52.8)
Unknown	7	5	2
Number of prior csDMARDs, *n* (%)			
0	4 (0.4)	2 (0.4)	2 (0.4)
1	649 (67.3)	338 (70.0)	311 (64.7)
2	241 (25.0)	105 (21.7)	136 (28.3)
≥3	70 (7.3)	38 (7.9)	32 (6.7)
Concomitant csDMARD at baseline, *n* (%)			
Any csDMARD	730 (75.7)	366 (75.8)	364 (75.7)
Any MTX	629 (65.2)	314 (65.0)	315 (65.5)
MTX alone	580 (60.2)	294 (60.9)	286 (59.5)
MTX and other csDMARD	49 (5.1)	20 (4.1)	29 (6.0)
csDMARD other than MTX	101 (10.5)	52 (10.8)	49 (10.2)
None	234 (24.3)	117 (24.2)	117 (24.3)

[a]Percentages calculated on non-missing values. csDMARD: conventional synthetic DMARD.

improvements incorporate many of the domains recommended by the GRAPPA-OMERACT working group to measure the impact of disease on patients with PsA [34].

In the current study, a difference in mean change from baseline at week 24 in SF-36 PCS and MCS composite scores was observed in the risankizumab group compared with the placebo group. Likewise, in the DISCOVER-2 trial in biologic-naïve patients with PsA, patients administered guselkumab reported greater mean changes from baseline at week 24 on SF-36 PCS and MCS composite scores than a placebo group [35]. Similar results were reported in the DISCOVER-1 trial in patients with active PsA who were biologic naïve or had previously received TNF inhibitor treatment [36], therefore supporting the benefits of an IL-23 inhibitor for patients with PsA in improving HRQoL.

In a qualitative study, patients with PsA reported experiencing a salient impact on work disability and effects on daily activities as a result of their disease-related symptoms [37]. Further research in patients with PsA found that each additional year of disease duration was significantly associated with being work-disabled [4]. Additionally, there are higher unemployment rates, increased healthcare costs and more comorbidities experienced in patients with PsA compared with the general population in the years following a diagnosis [5], and thus the importance of an effective and timely treatment to reduce the negative impact of the disease on patients' daily lives. The current study showed that treatment with risankizumab resulted in a greater improvement in performance at work (presenteeism domain of WPAI-PsA) and daily living activities (activity impairment domain of WPAI-PsA) compared with placebo, along with differences between groups on both domains. Conversely, absenteeism was not significantly affected. It is possible that a greater impact of treatment was observed on work-related outcomes other than absenteeism because patients in this study may have changed their job type or working hour to accommodate the functional limitations of their health condition. Overall, the findings of the current study provide evidence that IL-23 inhibitors, specifically risankizumab, can benefit aspects of HRQoL, including performance at work and effects on daily functioning.

Table 2 Number of patients and mean scores of PROs at baseline

PRO	Risankizumab 150 mg (*n* = 483)		Placebo (*n* = 481)	
	n	Mean (S.D.)	*n*	Mean (S.D.)
SF-36 PCS	482	35.2 (8.1)	477	35.2 (7.7)
SF-36 MCS	482	44.8 (10.7)	477	45.6 (10.9)
SF-36 domains				
Physical functioning	482	35.6 (9.6)	477	35.7 (9.4)
Role physical	482	36.7 (8.4)	477	37.0 (8.0)
Bodily pain	482	36.3 (7.5)	477	36.1 (7.1)
General health	482	38.6 (8.7)	477	39.1 (8.2)
Vitality	482	42.9 (9.2)	477	43.0 (9.0)
Social functioning	482	40.5 (10.4)	477	41.2 (9.9)
Role emotional	482	41.1 (11.1)	477	41.9 (11.0)
Mental health	482	42.6 (10.2)	477	43.3 (10.1)
FACIT-Fatigue	482	29.4 (11.3)	477	29.3 (11.2)
EQ-5D-5L index	482	0.61 (0.24)	477	0.59 (0.25)
EQ-5D-5L VAS	482	53.0 (20.9)	477	52.7 (21.2)
Pain VAS	482	57.1 (22.6)	479	57.1 (22.6)
PtGA VAS	482	57.9 (21.8)	479	57.4 (22.1)
WPAI-PsA (0–100)				
Overall work impairment[a]	265	49.9 (29.9)	251	46.6 (27.7)
Activity impairment	482	52.6 (25.1)	477	52.0 (24.4)
Absenteeism[a]	265	15.4 (28.6)	251	12.1 (24.9)
Presenteeism[a]	249	42.7 (25.5)	237	39.9 (24.0)

[a]Reported only for patients who were employed. EQ-5D-5L: EuroQoL-5 Dimension-5 Level; FACIT-Fatigue: Functional Assessment of Chronic Illness Therapy–Fatigue; MCS: mental component summary; PCS: physical component summary; PRO: patient-reported outcome; PtGA: Patient's Global Assessment of Disease Activity; SF-36: 36-Item Short-Form Health Survey; VAS: visual analogue scale; WPAI-PsA: Work Productivity and Activity Impairment.

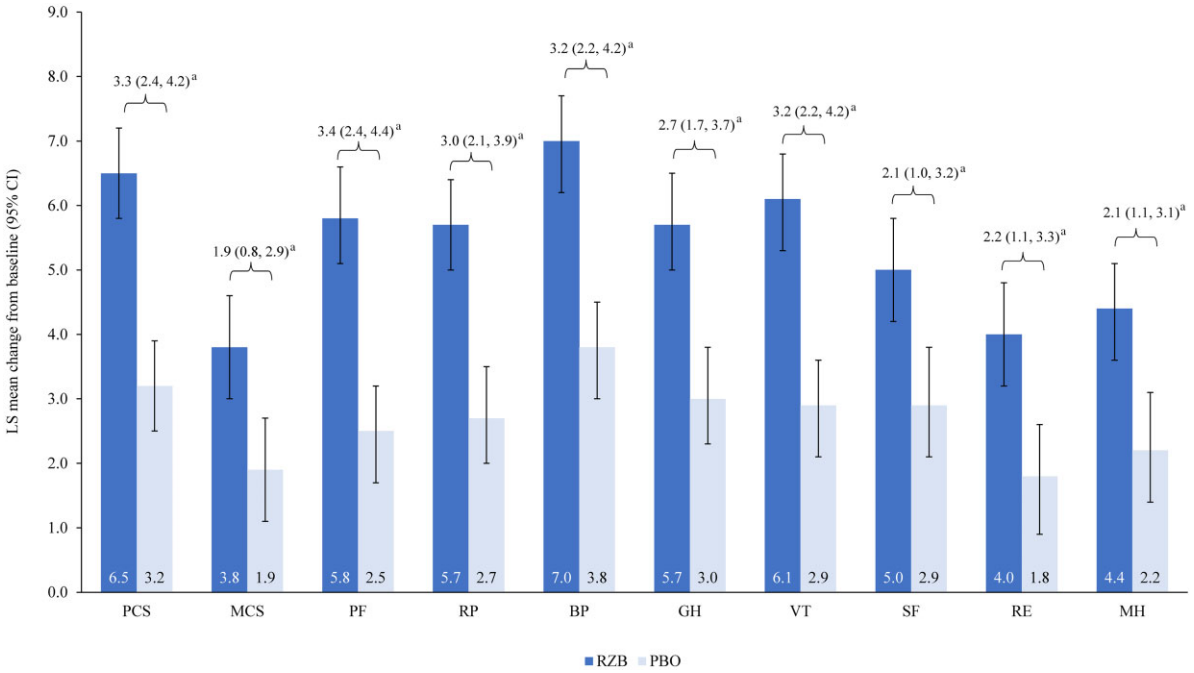
Table 3 LS mean change and difference in PRO scores from baseline at week 24

PRO	LS mean change (95% CI)		
	Risankizumab 150 mg (*n* = 483)	Placebo (*n* = 481)	Difference (95% CI)
FACIT-Fatigue	6.5 (5.6, 7.3)	3.9 (3.1, 4.7)	2.6 (1.5, 3.7)[a]
EQ-5D-5L index	0.14 (0.13, 0.16)	0.07 (0.05, 0.09)	0.07 (0.05, 0.09)[a]
EQ-5D-5L VAS	13.4 (11.4, 15.4)	7.7 (5.6, 9.7)	5.8 (3.1, 8.4)[a]
Pain VAS	–21.0 (−23.2, −18.8)	–10.2 (−12.5, −8.0)	–10.7 (–13.7, –7.8)[a]
PtGA VAS	–21.6 (−23.9, −19.4)	–10.5 (−12.8, −8.3)	–11.1 (–14.1, –8.1)[a]

[a]Nominal $P < 0.001$ for risankizumab *vs* placebo. EQ-5D-5L: EuroQoL-5 Dimension-5 Level; FACIT-Fatigue: Functional Assessment of Chronic Illness Therapy–Fatigue; LS: least squares; PRO: patient-reported outcome; PtGA: Patient's Global Assessment of Disease Activity; VAS: visual analogue scale.

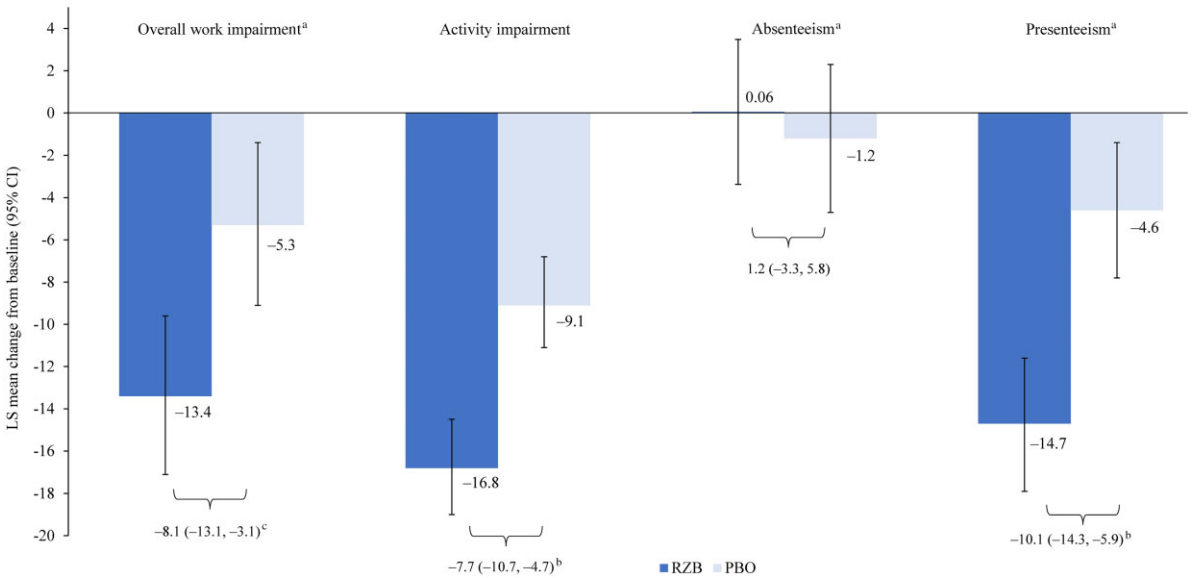
Other therapies and drug classes have been effective in improving HRQoL. For example, ixekizumab-treated patients reported significant improvement relative to placebo in the joint pain VAS, PtGA VAS, SF-36 and EQ-5D-5L through week 24 [38], comparable to the results of this study. Significant improvements on four subdomains of SF-36 were reported at month 3 with the JAK inhibitor tofacitinib; however, in the current study, there were improvements in comparison with a placebo group on all eight subdomains of SF-36 at week 24 [39]. In a comparison study of HRQoL among patients with rheumatoid arthritis, PsA and psoriasis, baseline PCS scores were low for patients with PsA, approaching 1.5 S.D. below the normative value of 50, comparable to this study [6]. After 24 weeks of treatment on the TNF inhibitor etanercept, patients' SF-36 PCS and MCS scores were significantly improved *vs* placebo [6]. Similarly, in the current study of risankizumab, treatment resulted in improvements in HRQoL at week 24 when compared with the placebo group. Additionally, treatment was

Fig. 1 LS mean change and difference (95% CI) in SF-36 component summary and domain scores from baseline at week 24



[a]Nominal $P < 0.001$ for risankizumab *vs* placebo. BP: bodily pain; GH: general health; LS: least squares; MCS: mental component summary; MH: mental health; PBO: placebo; PCS: physical component summary; PF: physical health; RE: role emotional; RZB: risankizumab; RP: role physical; SF: social functioning; SF-36: 36-Item Short-Form Survey; VT: vitality.

Fig. 2 LS mean change and difference (95% CI) in WPAI-PsA domain scores from baseline at week 24



[a]Reported only for patients who were employed. [b]Nominal $P < 0.001$ for risankizumab *vs* placebo. [c]Nominal $P < 0.01$ for risankizumab *vs* placebo.LS: least squares; PBO: placebo; RZB: risankizumab; WPAI-PsA: Work Productivity and Activity Impairment.

associated with greater improvements across all subdomains of SF-36 for patients with PsA at week 24 in both studies [6].

Risankizumab has been well tolerated and efficacious in patients with PsA and has demonstrated a favourable benefit/risk profile [19–21]. Efficacious treatment for PsA is important for reducing the burden of physical and psychological symptoms on patients, which could improve quality of care [8]. Furthermore, treating physical symptoms, both skin and joint, is important for optimal improvement of HRQoL [40]. This study provides evidence for the positive impact of risankizumab *vs* placebo on HRQoL PROs among patients with active PsA in the KEEPsAKE 1 trial.

A limitation of this study is that the results are not generalizable beyond the trial patient population. Additionally, no disease-specific questionnaires were used as the PROs measured were standard in PsA trial conduct at the time of planning this study. A strength of this study is that several PROs were used to reflect and capture the multiple burdens experienced by patients with PsA. Risankizumab treatment resulted in improvements in patients with active PsA who have csDMARD-IR compared with placebo treatment in HRQoL, fatigue, pain and work productivity. These results support the use of risankizumab by demonstrating a reduction in the impact of PsA on patients' HRQoL, in addition to symptomatic benefits.

Acknowledgements

Medical writing services were provided by Natalie Mitchell, of Fishawack Facilitate Ltd, part of Fishawack Health, and funded by AbbVie.

Funding: This work was supported by AbbVie. AbbVie sponsored the study; contributed to its design; and participated in the collection, analysis and interpretation of the data and in the writing, reviewing and approval of the publication. AbbVie funded the Rapid Service and Open Access of this publication. All authors had access to relevant data, and participated in the writing, review and approval of the publication. No honoraria or payments were made for authorship.

Disclosure statement: L.E.K. received fees for speaking and consultancy from AbbVie, Amgen, Biogen, Bristol Myers Squibb, Eli Lilly, Gilead, Janssen, MSD, Novartis, Pfizer and UCB, and ITT grants from Biogen, Eli Lilly, Janssen, Novartis, Pfizer and UCB. A.M.S., L.B., W.L. and A.E. are full-time employees of AbbVie and may hold AbbVie stock and/or stock options. K.P. has received honoraria or fees for serving on advisory boards or as a speaker or as a consultant, and grants as an investigator from AbbVie, Amgen, Astellas, Baxalta, Baxter, Boehringer Ingelheim, Bristol Myers Squibb, Celgene, Coherus, Dermira, Eli Lilly, Forward Pharma, Galderma, Genentech, GlaxoSmithKline, Janssen, Kyowa-Hakko Kirin, LEO Pharma, MedImmune, Merck-Serono, Merck Sharp & Dohme, Novartis, Pfizer, Regeneron, Roche, Sanofi-Genzyme, Stiefel, Sun Pharma, Takeda, UCB and Valeant. D.W. has received honoraria or fees for serving on advisory boards, as a speaker, and as a consultant from AbbVie, Novartis and Roche. F.B. has received grants from AbbVie, Pfizer, Roche, Chugai and Janssen, and consultant, speaker or advisory board fees from AbbVie, Pfizer, Roche, Chugai, UCB, BMS, Celgene, MSD, Novartis, Biotest, Janssen, Genzyme, Lilly, Boehringer and Sandoz.

Ethics: The protocol, informed consent forms, recruitment materials, and all participant materials were approved by an independent ethics committee or institutional review board at all study sites. All participants provided written informed consent prior to enrolment. The clinical study was conducted in accordance with the ethical principles that have their origin in the current Declaration of Helsinki and meets International Conference on Harmonization Good Clinical Practice and Good Epidemiology Practices and all applicable local regulatory requirements. All patient data were anonymized and complied with patient confidentiality requirements.

Data availability statement

AbbVie is committed to responsible data sharing regarding the clinical trials we sponsor. This includes access to anonymized, individual and trial-level data (analysis data sets), 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 review and approval of a research proposal and Statistical Analysis Plan (SAP) and execution of a Data Sharing Agreement (DSA). Data requests can be submitted at any time and 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://www.abbvie.com/our-science/clinical-trials/clinical-trials-data-and-information-sharing/data-and-information-sharing-with-qualified-researchers.html.

Supplementary data

Supplementary data are available at *Rheumatology* online.

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