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ORIGINAL RESEARCH

Secukinumab treatment showed improved quality of life in patients with chronic plaque psoriasis in Australia: Results from the HOPE study

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Abstract

Background: Psoriasis imposes a disease burden that can have a profound negative impact on patients' quality of life (QoL). HOPE was the first non-interventional study conducted in patients with severe chronic plaque psoriasis in Australia that evaluated health-related QoL in response to treatment with secukinumab.

Methods: HOPE was a prospective, open-label, single-arm, multicentre, non-interventional, exploratory study in patients with severe chronic plaque psoriasis in Australia. The study investigated the change in QoL, using the Dermatology Life Quality Index (DLQI), Assessment Quality of Life-8 Dimension questionnaire (AQoL-8D) and Psoriasis Area and Severity Index (PASI), and safety profile in response to treatment with secukinumab 300 mg SC weekly for 4 weeks followed by monthly maintenance for 58 weeks.

Results: At Week 14, the mean percentage reduction in total DLQI score from baseline was −82.4% ($n = 65$), which indicates a substantial improvement in QoL. This level of improvement was sustained up to Week ≥58, with a mean percentage change of −87.4%. The mean percentage change from baseline for AQoL-8D weighted total score decreased from Week 14 (41.1%) to Week 58 (35.2%), indicating an improvement in patients' QoL. A high proportion of patients achieved PASI 75/90/100 responses at Week 14 (97.0%/71.2%/34.8%), with rates sustained up to Week ≥58 (100%/87.9%/43.1%). The safety profile of secukinumab was favourable, with no cumulative or unexpected safety concerns.

Conclusion: Secukinumab treatment demonstrated a striking improvement in patients' QoL in the HOPE study, the first real-world study in patients with severe chronic plaque psoriasis in the Australian clinical setting.

KEYWORDS

AQoL-8D, Australia, DLQI, plaque psoriasis, quality of life, real world, secukinumab

INTRODUCTION

Psoriasis is an immune-mediated inflammatory disease with a wide spectrum of manifestations primarily in the skin and is characterised by erythematosquamous cutaneous lesions.[1,2] Psoriasis affects approximately 1.0%–3.0% of the general population,[2] 2.0%–4.0% of the population in western countries[3] and 2.3%–6.6% of the population in Australia.[4] Plaque-type psoriasis (psoriasis vulgaris) is the most common form of psoriasis manifestation.[5]

Psoriasis tends to be a long-term disease with a profound negative impact on patients' quality of life (QoL) and other psychosocial components such as stigmatisation, lack of acceptance from others and a necessity to cope with the chronic disease.[6] According to an Italian study,[7] psoriasis is often associated with a risk of physical disability and psychological discomfort.[7] The impact of psoriasis is concerning because patients have reduced physical and mental functioning, comparable to that associated with arthritis, hypertension, cardiovascular diseases, diabetes and depression.[8]

With the advent of biologics, significant progress has been achieved in the treatment of psoriasis with better efficacy and safety,[9] especially with recently approved biologics targeting tumour necrosis factors (TNF), interleukin-17 (IL-17) and interleukin-23 (IL-23).[10] Nine biologics are listed in the Australian Pharmaceutical Benefits Scheme (PBS)[11] for the treatment of psoriasis, including adalimumab, etanercept, infliximab, ustekinumab, secukinumab, ixekizumab, tildrakizumab, guselkumab and risankizumab. Etanercept, infliximab and adalimumab are TNF inhibitors that bind with TNF, a key pro-inflammatory cytokine in psoriasis.[12] Ustekinumab is an anti-IL-12/23 p40 antibody,[13] and ixekizumab is a humanised monoclonal antibody that effectively inhibits the interaction between IL-17A and its receptors.[14] Guselkumab, tildrakizumab and risankizumab are monoclonal antibodies that target the p19 subunit of IL-23 and neutralise its function.[15–17]

Secukinumab is a fully human monoclonal antibody that selectively neutralises IL-17A, a cornerstone cytokine involved in the development of psoriatic disease and its multiple manifestations, which include psoriatic arthritis and psoriasis localised to the nails, scalp, palms and soles.[1,18–21] Various clinical studies for secukinumab have demonstrated high and sustained efficacy and QoL through 5 years.[21–23] Superior efficacy was observed for secukinumab compared to etanercept in the FIXTURE study,[18] and ustekinumab in the CLEAR study[20] at Week 52 in patients with moderate-to-severe plaque psoriasis. A previous Spanish study examining safety with biologic therapy reported that nearly 30% of the patients receiving systemic therapy for psoriasis are ineligible for randomised controlled trials, emphasising the need for real-world data.[24] A number of real-world studies, including PROSE[25] and PROSPECT,[26] have evaluated the impact of secukinumab treatment for moderate-to-severe psoriasis on QoL, as assessed by patient-reported outcomes such as the Dermatology Life Quality Index (DLQI) and the Investigator's Global Assessment (IGA). However, the impact of secukinumab treatment on QoL remains unexplored in patients with severe chronic plaque psoriasis in Australian clinical settings.

HOPE was the first non-interventional study to evaluate the impact of secukinumab treatment on the QoL of patients in Australia using the DLQI and comparing the results with the Assessment of Quality of Life (AQoL-8D) questionnaire, a novel validated tool designed for the Australian population. Through the inclusion of the AQoL-8D and its comparison with the DLQI and PASI responses we provide novel information in the Australian context that can enhance our understanding of the patient's experience with severe psoriasis.

METHODS

Study design and patient population

HOPE was a prospective, open-label, single-arm, multicentre, non-interventional, exploratory study in patients with severe psoriasis. The study investigated change in QoL in the Australian clinical practice setting using the DLQI, AQoL-8D and Psoriasis Area and Severity Index (PASI) in response to treatment with secukinumab 300 mg subcutaneous (sc) weekly for 4 weeks followed by monthly maintenance evaluation for 58 weeks (Figure 1). Secukinumab was prescribed by an independent decision of the treating doctor prior to offering the patient the opportunity to participate in the study and followed the Australian prescribing label.

Endpoints of the study

The primary endpoint evaluated in the study was to demonstrate the change in DLQI at Week 14 in patients treated with secukinumab for severe chronic plaque psoriasis. Secondary endpoints evaluated were the change in AQoL-8D from baseline to Week 14 and the proportion of patients who achieved PASI75/90/100 responses at Week 14. The AQoL-8D questionnaire is a validated tool designed and developed for the Australian population by Monash University, Victoria, Australia. The AQoL-8D enhances the measurement sensitivity of psychosocial elements of health.[27] The questionnaire

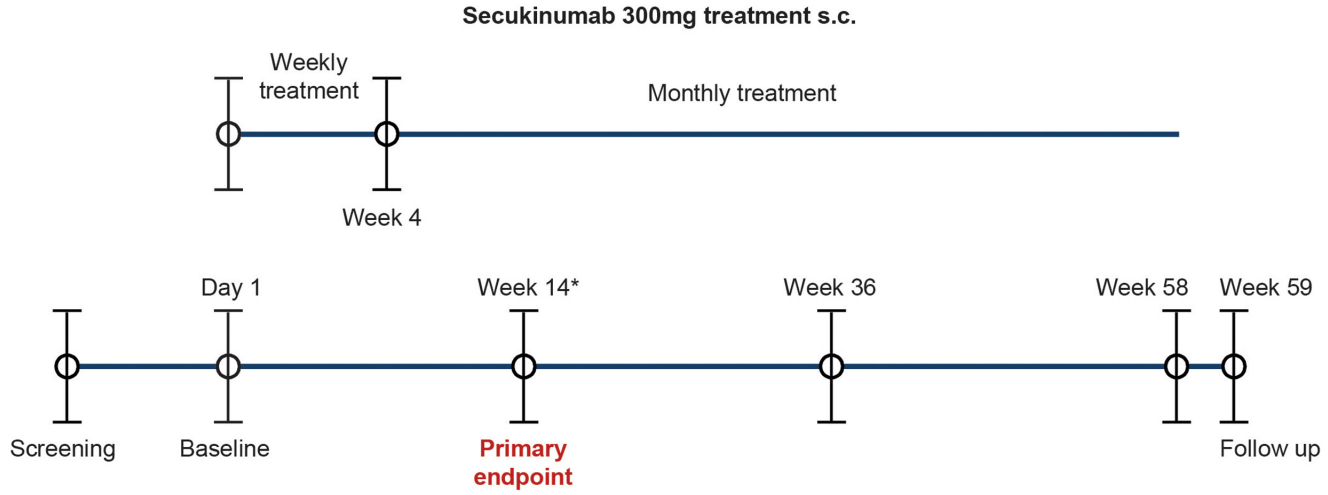

FIGURE 1 Study design of HOPE. *The assessment at week 14, the primary endpoint, was made between weeks 12 and 16 depending on the patient's regular visit schedule with their physician. N, number of patients; s.c., subcutaneous.

evaluates patients on both physical and psychosocial aspects of their health. It is a 35-item questionnaire, which covers 8 domains for evaluating patients during the past week. The physical dimension evaluates aspects of independent living, senses and pain (10 items), while the psychosocial dimension aspects are related to mental health, happiness, self-worth, coping with the disease and relationships (25 items).[27] The scores for each domain, the 2 super domains, and the total score were derived according to the instructions.

A post hoc analysis was carried out at Week ≥58 to include a larger patient population for measurement of PASI and DLQI responses. Exploratory endpoints evaluated were AQoL-8D, DLQI and PASI responses and adverse events up to Week 58. An additional exploratory endpoint was the change in Health assessment questionnaire-disability index (HAQ-DI) total score from baseline to Week 58 in patients with psoriatic arthritis at baseline.

Inclusion criteria

Male or female patients aged ≥18 years with chronic plaque-type psoriasis diagnosed for at least 6 months at baseline were included in the study. To qualify for secukinumab on the PBS scheme, patients needed a PASI score of >15 for whole body; or face, palm of hand or sole of foot with 2 of 3 PASI system subscores rated as severe or very severe or with ≥30% of the area affected.

Exclusion criteria

Patients with primary forms of psoriasis other than chronic plaque-type (e.g. pustular, erythrodermic and guttate psoriasis), drug-induced psoriasis (i.e. new onset or current exacerbation from, for example, beta-blockers, calcium channel inhibitors or lithium) and previous exposure to 2 or more biologic or targeted systemic therapies (ustekinumab, adalimumab, etanercept, infliximab, alefacept, briakinumab, efalizumab, golimumab, ixekizumab, brodalumab, tildrakizumab, guselkumab, apremilast, tofacitinib or risankizumab) were not included. Patients with an underlying condition (including but not limited to metabolic, haematologic, renal, hepatic, pulmonary, neurologic, endocrine, cardiac, infectious or gastrointestinal), which in the opinion of the investigator significantly immunocompromised the patient and/or placed the patient at unacceptable risk for receiving an immunomodulatory therapy, were also excluded.

Statistical analysis

Statistical data analyses were performed using SAS® (SAS Institute, Cary, NC, USA) version 9.4 or higher. All statistical tests were conducted against a 2-sided alternative hypothesis, with a significance level of 0.05.

RESULTS

Patient disposition

Of the 68 patients enrolled, 70.6% completed the study. In the remaining 29.4% patients, the most common reasons for discontinuation included lost to follow-up (17.6%), patient/guardian decision (4.4%) and adverse events or lack of efficacy (2.9%). The complete list of reasons for treatment discontinuation is detailed in Figure S1.

Demographics and baseline disease characteristics

The mean (SD) age of patients enrolled in the study at baseline was 48.2 (14.31) years and most patients (85.3%) were aged <65 years. The proportion of male patients was higher compared to female patients (55.9% vs. 44.1%). Most patients were Caucasian (73.5%) and 31 patients (45.6%) had a body mass index of ≥30 kg/m^2. Of the 68 patients included in the study, 20 (29.4%) also had psoriatic arthritis (Table 1).

At baseline, the total mean (SD) DLQI score was 15.3 (6.75), the PASI body score was 21.8 (8.04), the palmoplantar psoriasis (ppPASI) score was 12.5 (18.56) in 16 patients with recorded palmoplantar psoriasis, and the PASI face score was 8.9 (8.94) in 27 patients with recorded facial plaque psoriasis. The mean (SD) time since first diagnosis of plaque-type psoriasis was 18.8 (11.30) years. All patients had received previous psoriasis therapy; 98.5% of patients received non-biologic systemic therapy, 80.9% of patients received phototherapy and 10.3% of patients received biologic systemic therapy (Table 1).

Quality of life

At Week 14, the observed mean (SD) DLQI total score reduced to 2.9 (4.5) compared to 15.3 (6.8) at baseline (Figure 2a). The mean percentage change in DLQI total score was −82.4% at Week 14, indicating a substantial improvement in patients' QoL (Figure 2b). The extent of the improvement in DLQI total score was sustained up to Week ≥58, at which the mean (SD) DLQI total score was 1.9 (3.1) and the mean percentage change in DLQI total score was −87.4%, as evaluated by post hoc analysis (Figure 2a,b).

At Week 14, a significant change of 0.15 (0.04) (95% CI: 0.1, 0.2; $P < 0.0001$) in least squares (LS) mean (standard error of the mean [SEM]) for AQoL-8D weighted total scores was observed from baseline and the mean (standard error [SE]) change was 0.2 (0.02). Similarly, at Week 58 there was a significant change of 0.18 (0.04) (95% CI: 0.11, 0.25; $p < 0.05$) in LS mean (SEM) from baseline and the mean (SE) change was 0.17 (0.03). The mean percentage change from baseline for the AQoL-8D weighted total score to Week 14 was 41.1% and to Week 58, it was 35.2%, indicating sustained improvement in patients' QoL (Figure 3). The AQoL-8D unweighted total score mean (SD) was 81.02 (19.29) at baseline and at Week 14 it decreased to 65.05 (18.90), a percentage change of −18.75%. At Week 58, a statistically significant change of −16.17 (3.26) (95% CI: −22.66, −9.69; $p < 0.05$) in LS mean (SEM)

TABLE 1 Baseline demographics and disease characteristics

Characteristic	AIN457 300 mg, *N* = 68; *n* (%)
Age group – *n* (%)	
<65 years	58 (85.3)
≥65 years	10 (14.7)
Sex- *n* (%)	
Male	38 (55.9)
Race – *n* (%)	
Caucasian	50 (73.5)
Asian	10 (14.7)
Other[a]	8 (11.8)
Weight category – *n* (%)	
<90 kg	40 (58.8)
≥90 kg	27 (39.7)
Missing	1 (1.5)
Weight	
n	67
Mean (SD)	90.0 (28.21)
BMI (kg/m^2)	
n	67
Mean (SD)	30.9 (7.87)
Baseline DLQI total score	
n	67
Mean (SD)	15.3 (6.75)
Baseline PASI body score	
n	66
Mean (SD)	21.8 (8.04)
Baseline ppPASI (palmoplantar score)	
n	16
Mean (SD)	12.5 (18.56)
Baseline PASI face score	
n	27
Mean (SD)	8.9 (8.94)
Time since first diagnosis of plaque-type psoriasis (years)	
n	67
Mean (SD)	18.8 (11.30)
Previous psoriasis therapy taken, *n* (%)	
Yes	68 (100.0)
Previous biologic systemic therapy, *n* (%)	
Yes	7 (10.3)
No	61 (89.7)
Previous non-biologic systemic therapy, *n* (%)	
Yes	67 (98.5)
No	1 (1.5)

Abbreviations: BMI, body mass index; DLQI, Dermatology Life Quality Index; PASI, Psoriasis Area and Severity Index; ppPASI, palmoplantar pustulosis PASI; SD, standard deviation.

[a]Includes: Pacific Islander (1), Afghan (1), Central American (1), Indian (1), Indigenous Australian (2), South American (1), White/Indigenous Australian (1).

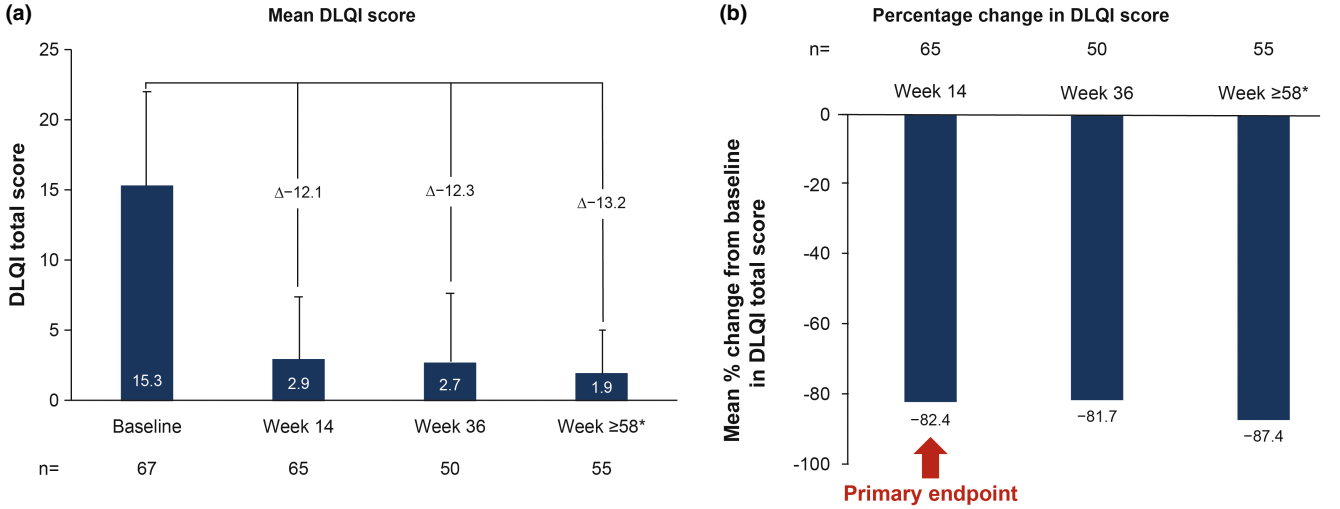

FIGURE 2 Achievement of the primary endpoint at week 14 and the sustained effect up to week ≥ 58 (post hoc analysis). (a) Change in mean total DLQI score from baseline up to week ≥ 58. *Week ≥58 includes data for patients who attended the clinic for a week 58 visit or a follow-up appointment after the week 58 visit window. Δ, mean change from baseline in DLQI total score; DLQI, dermatology life quality index; N, number of patients. (b) Increased percentage change in DLQI score up to week ≥ 58. *Week ≥58 includes data for patients who attended the clinic for a week 58 visit or a follow-up appointment after the week 58 visit window. DLQI, dermatology life quality index.

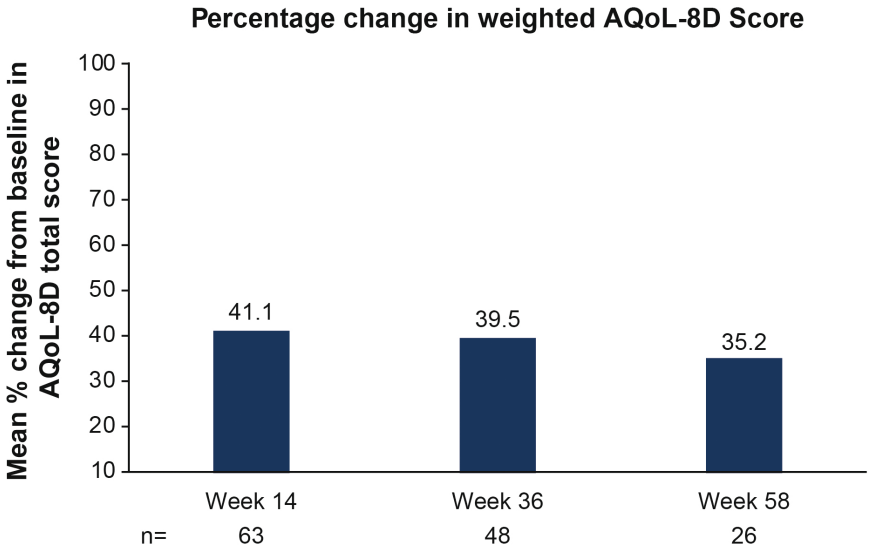

FIGURE 3 Assessment of QoL using change in weighted AQoL-8D total score up to week 58. AQoL-8D, assessment of quality of life Questionnaire-8 dimensions.

for AQoL-8D unweighted total scores was observed from baseline and the mean (SE) change was −17.22 (2.68).

PASI responses

At Week 14, of the 66 patients evaluated, PASI 75 response was achieved by 97% of patients (95% CI: 89.5, 99.6), PASI 90 response was achieved by 71.2% (95% CI: 58.8, 81.7) and PASI 100 response was achieved by 34.8% (95% CI: 23.5, 47.6) (Figure 4). Of the 58 patients evaluated at Week ≥58, sustained improvements were observed in PASI 75/90/100 responses (100%/87.9%/43.1%, respectively) in post hoc analysis using last observation carried forward (LOCF) method.

Health assessment Questionnaire-disability index (HAQ-DI)

No significant difference was observed in change from baseline in HAQ-DI at Week ≥58. The mean (SD) change from baseline in HAQ-DI total score was −0.2 (0.34) at Week 14, −0.2 (0.47) at Week 36 and −0.1 (0.54) at Week ≥58.

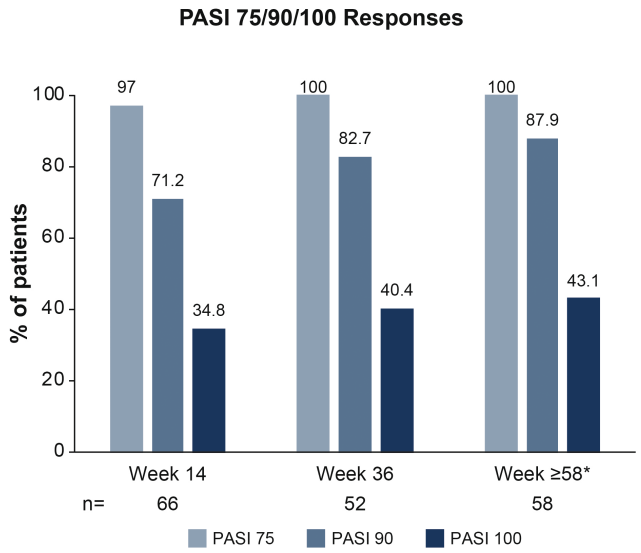

FIGURE 4 Achievement of PASI 75/90/100 responses by severe chronic plaque psoriasis patients including post hoc analysis after week 58 (LOCF). *Week ≥58 includes data for patients who attended the clinic for a week 58 visit or a follow-up appointment after the Week 58 visit window. LOCF, last observation carried forward; PASI, psoriasis area and severity index.

Safety

The safety profile of secukinumab was favourable, with no cumulative or unexpected safety concerns. No deaths were reported in the study. Treatment-emergent serious adverse events were rectal haemorrhage, appendicitis, viral infection, basal cell carcinoma and asthma (1.5% each). Overall, 67.6% patients reported at least one treatment-emergent adverse event (TEAE). Most common TEAEs, irrespective of study treatment relationship, by primary system organ class, were infections and infestations (32.4%), skin and subcutaneous tissue disorders (20.6%), musculoskeletal and connective tissue disorders (13.2%), respiratory, thoracic and mediastinal disorders (14.7%), general disorders and administration site conditions (11.8%), neoplasms benign, malignant and unspecified (including cysts and polyps) (8.8%), investigations (7.4%), metabolism and nutrition disorder (7.4%), and gastrointestinal disorders (7.4%). Table 2 describes the TEAEs by preferred term. The most common TEAEs (≥2%) suspected to be study treatment-related were oropharyngeal pain (5.9%), rhinorrhoea (4.4%), cough (2.9%), influenza (2.9%) and psoriasis (2.9%). Treatment-emergent adverse events leading to study drug discontinuation were tinea pedis (one patient) and psoriasis (one patient).

TABLE 2 Treatment-emergent adverse events regardless of study treatment relationship, by primary system organ class and preferred term (safety set)

Preferred term	Secukinumab 300 mg, *N* = 68, *n* (%)
Number of subjects with at least 1 adverse event	46 (67.6)
Oropharyngeal pain	5 (7.4)
Psoriasis	4 (5.9)
Psoriatic arthropathy	4 (5.9)
Upper respiratory tract infection	4 (5.9)
Influenza	3 (4.4)
Rhinorrhoea	3 (4.4)
Vitamin D deficiency	3 (4.4)
Fungal skin infection	2 (2.9)
Nasopharyngitis	2 (2.9)
Sinusitis	2 (2.9)
Viral upper respiratory tract infection	2 (2.9)
Erythema	2 (2.9)
Cough	2 (2.9)
Back pain	2 (2.9)
Osteoarthritis	2 (2.9)
Influenza-like illness	2 (2.9)
Peripheral swelling	2 (2.9)
Seborrhoeic keratosis	2 (2.9)
Gastroesophageal reflux disease	2 (2.9)
Nausea	2 (2.9)

Abbreviation: TEAEs, treatment-emergent adverse events.

DISCUSSION

Psoriasis is a chronic debilitating inflammatory disease[22] and patients suffer from a significant psychosocial burden due to the disease.[9] A breakthrough in the treatment of moderate-to-severe psoriasis was achieved with biologics.[10] Of the recently approved biologics being used for the treatment of psoriasis, secukinumab has consistently demonstrated greater efficacy and improved patient-reported outcomes in a number of randomised controlled trials, such as the Phase 3b CLEAR[20] study, a 52-week trial conducted in Chinese ethnicity[28] (NCT03066609, EudraCT2016-000524-25), and the 16-week CLARITY[29] study conducted in patients with moderate-to-severe plaque psoriasis. However, the impact on QoL outcomes and response to secukinumab treatment remained insufficiently explored in patients with severe chronic plaque

psoriasis in Australia. HOPE evaluated health-related QoL, using the DLQI and AQoL-8D, in the Australian clinical setting in patients with severe chronic plaque psoriasis treated with secukinumab.

Patient-reported outcomes (PROs) are used extensively by healthcare professionals to measure the impact of disease on QoL.[30] Tools such as DLQI are useful as they quantify the impact of psoriasis on QoL, considering the significant physical and psychological impact associated with the disease.[30] Assessing the impact of a disease on patients' QoL requires measuring disease-specific parameters such as symptoms, as well as global parameters of wellbeing such as physical functioning.[8] The HOPE study evaluated the psychosocial components of patients with severe chronic plaque psoriasis using the DLQI and compared these results with the AQoL-8D questionnaire (a validated tool designed for the Australian population) and PASI response. The study focused on overall QoL as assessed by the DLQI in patients with severe chronic plaque psoriasis in the Australian real-world setting and provides insights into how subsequent therapy improves their QoL.

A significant improvement in QoL with secukinumab treatment was observed in the study at Week 14 measured through PROs such as the DLQI and AQoL-8D. A significant change was also noted in all DLQI functional domain scores (scores of symptoms and feelings, daily activity, leisure, work and school, personal relationship and treatment) from baseline until Week 14. The rate of improvement in DLQI total score at Week 14 from baseline was maintained until Week 58, and a similar extent of improvement was seen in all DLQI functional domains at Weeks 14, 58 and ≥58. A statistically significant change was observed in both unweighted and weighted (physical super dimension scores and psychosocial super dimension score) total scores of AQoL-8D from baseline until Weeks 14 and 58.

Overall, a consistent improvement was observed in the proportion of patients who achieved PASI 75/90/100 from Week 14 onwards. At Weeks 36 and 58, a high proportion of patients achieved PASI 75, PASI 90 and PASI 100 responses. These findings were consistent with the pivotal randomised controlled Phase 3 trials,[18] which include ERASURE, FIXTURE, FEATURE and JUNCTURE.

No new safety signal or any change in the known frequency of adverse events was observed during the study that could alter the current benefit–risk assessment of secukinumab.

A single-arm study design could be a limitation due to the inability to distinguish between a treatment effect and a placebo effect. The number of patients analysed in this study was also small. The non-interventional study design lacks the structure and validity of a randomised controlled trial. To address this, mandated data collection was aligned with PBS qualifying and continuing visit windows.

CONCLUSION

Efficacy responses to secukinumab in the HOPE study were consistent with reported outcomes in the Phase 3 clinical trial studies. Patients reported a substantial improvement in their QoL, as measured by the organ-specific measurement tool DLQI and the AQoL-8D (a validated tool for the Australian population, designed to improve the evaluation of health services that have an impact on the psychosocial aspects of QoL), after 14 and 58 weeks of secukinumab treatment, with psoriasis having only a small effect on their QoL at the observed time points. This was attributed to the improvements in their objective measure of clinical disease severity (PASI). The study did not report any new safety signals for patients on secukinumab treatment.

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CONFLICT OF INTEREST

P. Foley has served on the advisory board and/or as a consultant/investigator and/or received research grant/speaker's honoraria/travel grants from AbbVie, Akaal, Amgen, Arcutis, Argenx, Aslan, Astra Zeneca, BMS, Boehringer Ingelheim, Botanix, Celgene, Celtaxsys, CSL, Cutanea, Dermira, Eli Lilly and Company, EVELO Biosciences, Galderma, Geneseq, GenesisCare, GSK, Hexima, Janssen, Kymab, Leo Pharma, Mayne Pharma, MedImmune, Melaseq/Geneseq, Merck, Novartis, Pfizer, Regeneron Pharmaceuticals Inc., Reistone, Roche, Sanofi, Sun Pharma, Teva, UCB Pharma, Valeant, and Wintermute. **L. Spelman** has served on advisory boards for AbbVie, Eli Lilly, Galderma, Janssen and Novartis; has served as an investigator for AbbVie, Amgen, Anacor, Ascend Biopharmaceuticals, Astellas, Australian Wool Innovation Limited, Blaze Bioscience,

Boehringer Ingelheim, BMS, Botanix, Celgene, Dermira, Eli Lilly, Galderma, Genentech, GlaxoSmithKline, Janssen, Kythera, Leo Pharma, Mayne, Merck, Novartis, Pfizer, Phosphagenics, Regeneron, Sanofi, Sun Pharmaceuticals, Trius, and UCB; and has received sponsored travel from Abbott, Novartis, and Janssen. **D.F. Murrell** has served as an advisory board member, investigator and/or received grants from Pfizer, Janssen, Sun Pharma, Novartis, Abbvie, Sanofi, Regeneron, Principiabio, Arena, AstraZeneca, Roche, Amryt, CastleCreek, Shire, Genentech, Anacord, Astellas, BMS, Botanix, Dermira, GSK, Kythera, Leo Pharma, UCB. ArgenX, Scioderm and Lilly. **E. Mate** and **R. Tronnberg** are employees of Novartis Pharmaceuticals Australia Pty. Ltd. **P. M. Lowe** has no disclosures to declare.

ETHICAL APPROVAL

The study protocol was approved by the Bellberry Ltd independent human research ethics committee. The study was conducted according to the Declaration of Helsinki.

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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