ORIGINAL ARTICLE

Secukinumab demonstrates high sustained efficacy and a favourable safety profile in patients with moderate-to-severe psoriasis through 5 years of treatment (SCULPTURE Extension Study)

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Abstract

Background Secukinumab, a fully human monoclonal antibody that selectively neutralizes IL-17A, has been shown to have significant efficacy and a favourable safety profile in the treatment of moderate-to-severe psoriasis and psoriatic arthritis.

Objective To assess the efficacy and safety of secukinumab through 5 years of treatment in moderate-to-severe psoriasis.

Methods In the core SCULPTURE study, Psoriasis Area and Severity Index (PASI) 75 responders at Week 12 continued receiving subcutaneous secukinumab until Year 1. Thereafter, patients entered the extension phase and continued treatment as per the core trial. Treatment was double-blinded until the end of Year 3 and open-label from Year 4. Here, we focus on the 300 mg fixed-interval (every 4 weeks) treatment, the recommended per label dose. Efficacy data are primarily reported as observed, but multiple imputation (MI) and last observation carried forward (LOCF) techniques were also undertaken as supportive analyses.

Results At Year 1, 168 patients entered the extension study and at the end of Year 5, 126 patients completed 300 mg (every 4 weeks) treatment. PASI 75/90/100 responses at Year 1 (88.9%, 68.5% and 43.8%, respectively) were sustained to Year 5 (88.5%, 66.4% and 41%). PASI responses were consistent regardless of the analysis undertaken (as observed, MI, or LOCF). The average improvement in mean PASI was approximately 90% through 5 years compared with core study baseline. DLQI (dermatology life quality index) 0/1 response also sustained through 5 years (72.7% at Year 1 and 65.5% at Year 5). The safety profile of secukinumab remained favourable, with no cumulative or unexpected safety concerns identified.

Conclusion Secukinumab 300 mg treatment delivered high and sustained levels of skin clearance and improved quality of life through 5 years in patients with moderate-to-severe psoriasis. Favourable safety established in the secukinumab phase 2/3 programme was maintained through 5 years.

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Conflicts of interest

R. Bissonnette is an investigator, advisory board member, speaker, consultant for and/or has received honoraria or grants from AbbVie, Amgen, Boehringer Ingelheim, BMS, Celgene, Eli Lilly, Galderma, GSK-Stiefel, Immune Tolerance, Incyte, Janssen, Kineta, Leo Pharma, Merck, Novartis, Pfizer and Xenoport. R. Bissonnette is also a shareholder of Innovaderm Research; T. Luger has received honoraria as an advisory board member from

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AbbVie, Amgen, CERIES, Celgene, Clinuvel, Lilly, Galderma, Janssen-Cilag, La Roche-Posay, MEDA Pharma, Mundipharma, Pfizer, Sandoz, Symrise; grants as an investigator from Biogen Idec, Janssen-Cilag, MEDA Pharma, Pfizer and Wolff; honoraria as a speaker/consultant from Novartis, AbbVie, Astellas, Galderma, La Roche-Posay, MEDA Pharma and Janssen-Cilag; and honoraria as a clinical trial investigator from Janssen-Cilag, Lilly, Novartis and Pfizer; Institution of D Thaçi has received fees for performing clinical trials from AbbVie, Amgen, Boehringer Ingelheim, Celgene, Dignity, Eli Lilly, Galderma, GlaxoSmithKline, LEO Pharma, Janssen-Cilag, Maruho, MSD, Novartis, Pfizer and Sandoz; received honoraria as a consultant from AbbVie, Celgene, Dignity, Galapagos, Novartis, Pfizer and Xenoport; and received honoraria as a scientific advisory board member from AbbVie, Amgen, Boehringer Ingelheim, Celgene, GlaxoSmithKline, Janssen-Cilag, Lilly, Medac, Novartis, Pfizer and Hexal-Sandoz; D. Toth has received honoraria as an advisory board member, investigator and/or speaker from AbbVie, Amgen, Celgene, Eli Lilly and Company, Galderma, Genentech, Janssen, LEO Pharma, Merck, Novartis, Pfizer and Regeneron; A. Lacombe, R. Mazur, M. Patekar, P. Charef and M. Milutinovic are employees of Novartis Pharma AG, Basel, Switzerland; S. Xia is an employee of Beijing Novartis Pharma Co. Ltd., Shanghai, China; C. Leonardi has received honoraria as a consultant for AbbVie, Amgen, Dermira, Janssen, Eli Lilly, LEO, Sandoz, UCB and Pfizer; as an investigator for Actavis, AbbVie, Amgen, Celgene, Coherus, Dermira, Eli Lilly, Galderma, Janssen, Merck, Pfizer, Sandoz, Stiefel, LEO, Novartis and Wyeth and has participated in speaker bureaus for AbbVie, Celgene and Lilly. U. Mrowietz has been working as an advisor and/or presenter and/or recipient of research support and/or participant at clinical studies for the following companies: AbbVie, Almirall, Amgen, Celgene, Dr. Reddy's, Eli Lilly, Formycon, Forward Pharma, Janssen, Leo Pharma, Medac, MSD, Novartis, VBL and Xenoport.

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Introduction

Psoriasis is a chronic immune-mediated skin disease characterized by scaly erythematous plaques that potentially requires lifelong disease management. Secukinumab, a fully human monoclonal antibody that selectively neutralizes IL-17A, has been shown to have significant efficacy in the treatment of moderate-to-severe psoriasis and psoriatic arthritis, demonstrating high levels of efficacy with a favourable safety profile.[1–5] The recommended (per label) dose of secukinumab is 300 mg subcutaneous.

As psoriasis is a condition requiring long-term treatment, longitudinal data establishing the efficacy and safety of approved therapies are important for physicians and patients. Having previously demonstrated the sustained efficacy and favourable safety of secukinumab through 3 years of treatment in moderate-to-severe psoriasis patients;[6] here, we present data through 5 years.

Materials and methods

Study design

In the core SCULPTURE study, Psoriasis Area and Severity Index (PASI) 75 responders (≥75% improvement from baseline PASI score) at Week 12 were randomized to fixed-interval (FI; 150 mg or 300 mg), or retreatment-as-needed (RAN; 150 mg or 300 mg) regimens, as described previously in Mrowietz *et al.*[7] The 300 mg FI cohort received subcutaneous secukinumab every 4 weeks. Patients who completed 52 weeks of treatment continued into the extension study (CAIN457A2304E1) and received the same blinded maintenance treatment regimen and dose up to the end of Year 3. The study was open-label from Year 4 with treatment mainly self-injected at home; patients attended site visits every 12–16 weeks. No additional active therapies (topicals or systemic) were permitted in the extension study with the exception of topical treatments applied to the face, scalp and/or genitoanal area for up to 14 consecutive days. Here, we report long-term results for the secukinumab 300 mg FI arm only, which is the recommended labelled dose regimen.

Inclusion/exclusion criteria

Eligibility criteria for the SCULPTURE core study have been described in detail previously.[7] Briefly, subjects were age ≥18 years and had a diagnosis (≥6 months prior to randomization) of chronic moderate-to-severe plaque psoriasis [absolute PASI score ≥12; Investigator's Global Assessment 2011 modified version (IGA mod 2011) score of ≥3; body surface area (BSA) involvement ≥10%]. Additionally, subjects were required to have a history of inadequate psoriasis control with topical treatments, phototherapy, systemic therapy or a combination of these.[7] Subjects were excluded from the study if they had any form of psoriasis other than chronic plaque-type psoriasis, if they had current drug-induced psoriasis or if they had previously used secukinumab or any drug that targets IL-17 or the IL-17 receptor.

Study objectives

The objectives of this study were to assess the long-term efficacy and safety of secukinumab through 5 years of treatment. Efficacy assessments included PASI responses, absolute PASI and BSA score, dermatology life quality index (DLQI) 0/1 response (no effect of skin disease on quality of life), Health Assessment Questionnaire Disability Index (HAQ-DI) response (an improvement of at least 0.3 score points compared to baseline; undertaken for patients with concomitant psoriatic arthritis only). Safety assessments consisted of adverse event (AE) assessment, physical examination, electrocardiograms and monitoring of vital signs and laboratory values.

Statistical methods

Primary analyses for all efficacy measures (PASI 75/90/100 responses, mean absolute and % change from baseline for PASI and BSA, absolute PASI ≤1/≤2/≤3/≤5 responses, BSA ≤1/≤2/≤3/≤5 responses, DLQI 0/1 responses and HAQ-DI responses) were undertaken using observed values without imputation of missing values. Additionally, multiple imputation (MI) and last observation carried forward (LOCF) were used as a sensitivity analyses for PASI and BSA measures. The as-observed analysis assessed treatment efficacy for patients who completed an assessment at each visit only. The MI analysis evaluated treatment efficacy for all randomized patients by imputing the missing values based on the missing-at-random assumption, while the LOCF analysis imputed the missing values by the last available measurement for each patient. Safety events were analysed per year using exposure-adjusted incidence rates (patient incidence rates per 100 patient-years). A patient with multiple occurrences of the same AE in a year interval was counted once, while a patient with multiple occurrences of the same AE in different year intervals was counted for each year.

Study oversight

The extension study protocol was approved by the institutional review board or ethics committee at each participating site, and the study was conducted in accordance with the ICH Harmonized Tripartite Guidelines for Good Clinical Practice and with the ethical principles of the Declaration of Helsinki. US sites maintained compliance with HIPAA regulations. All eligible patients provided written consent. The study is registered with ClinicalTrials.gov (NCT01640951).

Results

Baseline characteristics and subject disposition

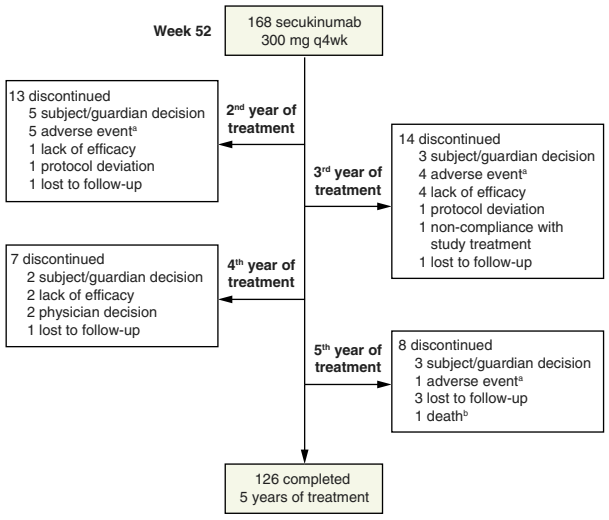
Baseline demographics and clinical characteristics of extension study patients (n = 168) are presented in Table 1. The mean PASI of 23.5, BSA involvement of 33.1%, mean DLQI of 13.1, and a mean time since first psoriasis diagnosis of 19.1 years, indicated a high disease severity at baseline. Additionally, 19.6% of patients had a diagnosis of psoriatic arthritis.

Table 1 Characteristics of extension study subjects at core study baseline

Characteristics	Secukinumab 300 mg FI (n = 168)
Age, years (Mean ± SD)	48.5 ± 12.5
Gender-Male, *n* (%)	118 (70.2)
Race-Caucasian, *n* (%)	132 (78.6)
Bodyweight, kg (Mean ± SD)	85.5 ± 21.3
BMI, kg/m^2 (Mean ± SD)	28.7 ± 6.2
Time since first psoriasis diagnosis, years (Mean ± SD)	19.1 ± 13.4
PASI (Mean ± SD)	23.5 ± 8.8
BSA affected, % (Mean ± SD)	33.1 ± 18.9
DLQI (Mean ± SD)	13.1 ± 7.4
Psoriatic arthritis present, *n* (%)	33 (19.6)
Previous systemic treatment, *n* (%)	
Any	120 (71.4)
Biologic	56 (33.3)

BMI, body mass index; BSA, body surface area; DLQI, Dermatology Life Quality Index; FI, fixed-interval; *n*, number of evaluable subjects; PASI, Psoriasis Area and Severity Index; SD, standard deviation.

On completion of the 1-year core study, 168 subjects in the 300 mg FI cohort entered the extension study; at the end of Year 5, 126 subjects had completed the treatment phase of the study (Fig. 1).



[a]The adverse events leading to discontinuation, by Medical Dictionary for Regulatory Activities (MedDRA) preferred term, were hepatic cirrhosis, eczema, gastro-oesophageoal reflux disease, ulcerative colitis (exacerbation of previously existing ulcerative colitis), cholangiocarcinoma, granulomatosis with polyangiitis, blood alkaline phosphatase increased, breast cancer, and Clostridium difficile colitis.
[b]Death was due to a major adverse cardiovascular event (MACE), which was not considered by the investigators to be related to study drug; patient had ≥2 pre-existing MACE risk factors. q4wk, every 4 weeks

Figure 1 Subject disposition in the secukinumab 300 mg fixed-interval treatment arm.

Efficacy and patient reported outcomes

Efficacy outcomes – relative to baseline Psoriasis Area and Severity Index 75, 90 and 100 response rates sustained from Year 1 (88.9%, 68.5% and 43.8%, respectively) to Year 5 (88.5%, 66.4% and 41%; Fig. 2 and Table S1). PASI responses were consistent across the different analyses undertaken: PASI 75, 90 and 100 response rates were sustained to Year 5 in the MI (80.1%, 58.6% and 35.6%) and LOCF (79.2%, 59.5% and 37.5%) analyses (Fig. 2 and Table S1).

Secukinumab improved psoriasis on average by 90% through 5 years; the mean improvement in mean absolute PASI from baseline to Year 1 was 91.1%, and from baseline to Year 5 was 90.1% (Fig. 3). Similarly, there were sustained improvements in mean absolute BSA from baseline to Year 1 (92.2%) and Year 5 (91.8%) (Fig. 4).

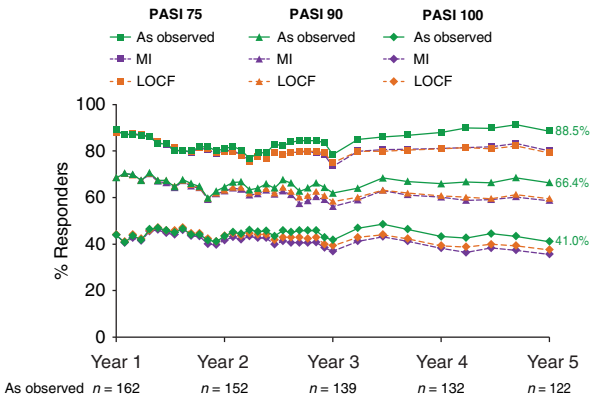
Efficacy outcomes – absolute values Absolute PASI ≤5/≤3/≤2/≤1 responses sustained from Year 1 (87.7%, 74.1%, 67.9% and 58.6%, respectively) through to Year 5 (84.4%, 75.4%, 66.4% and 53.3%; Fig. 5 and Table S2). Similarly, PASI ≤5/≤3/≤2/≤1 responses sustained to Year 5 in the MI (76.4%, 66.9%, 58.4% and 47%) and LOCF (76.2%, 69%, 60.1% and 48.2%) analyses (Fig. 5 and Table S2).

Mean absolute PASI at Year 1 and Year 5 was 2.1 and 2.4, respectively, indicating long-term maintenance of efficacy (Fig. 6). The maintenance of individual patients' absolute PASI through 5 years of treatment can be observed in a time-lapse video provided as Video S1.

Body surface area ≤5/≤3/≤2/≤1 response rates sustained from Year 1 (85.2%, 77.2%, 73.5% and 60.5%, respectively) through to Year 5 (85.2%, 78.7%, 71.3% and 62.3%; Fig. 7 and Table S3). Similarly, these response rates sustained to Year 5 in the MI (76.9%, 69.8%, 62.8% and 54.5%) and LOCF (78%, 71.4%, 63.7% and 56.5%) analyses (Fig. 7 and Table S3).

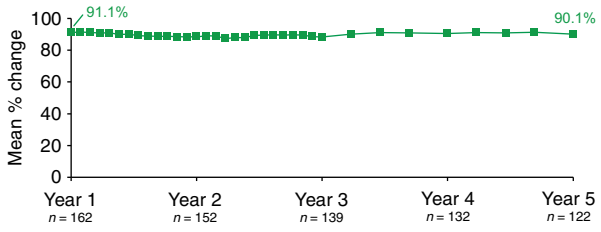
Mean absolute BSA was consistently low through 5 years of treatment (2.5% at Year 1 and 2.8% at Year 5; Fig. 8).

Patient-reported outcomes (DLQI and HAQ-DI) Secukinumab lead to high and sustained improvement in patients' quality of life affected by their skin and/or concomitant psoriatic arthritis



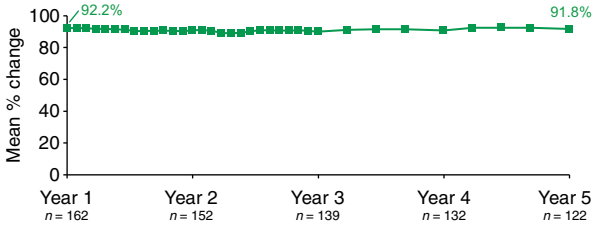
LOCF, last observation carried forward; MI, multiple imputation; n, number of evaluable patients in the as-observed analysis (the number of evaluable patients in the MI and LOCF analyses was 168 at each time point); PASI, Psoriasis Area and Severity Index score

Figure 2 Percentage of patients with PASI 75/90/100 response from Year 1 to Year 5.



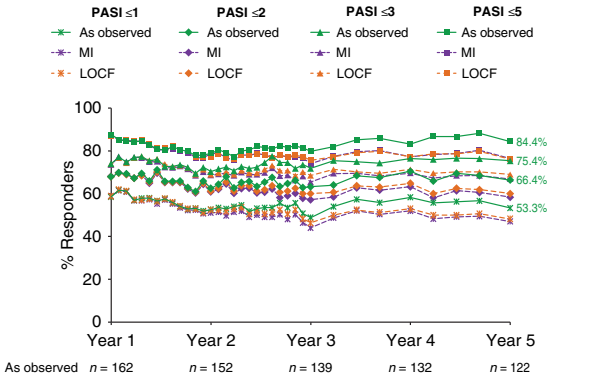
As-observed analysis with n being the number of evaluable patients; PASI, Psoriasis Area and Severity Index score

Figure 3 Mean percentage change (improvement) from baseline in mean absolute PASI.



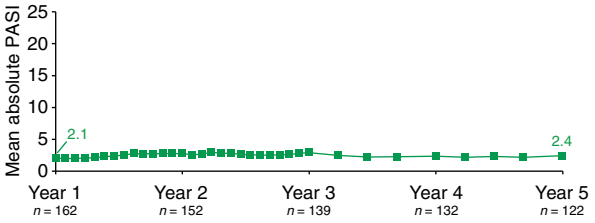
As-observed analysis with n being the number of evaluable patients; BSA, body surface area

Figure 4 Mean percentage change (improvement) from baseline in mean BSA.



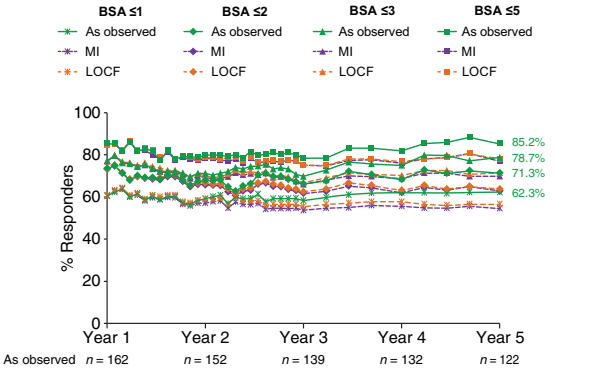
LOCF, last observation carried forward; MI, multiple imputation; n, number of evaluable patients in the as-observed analysis (the number of evaluable patients in the MI and LOCF analyses was 168 at each time point); PASI, Psoriasis Area and Severity Index score

Figure 5 Percentage of patients with mean absolute PASI responses by category from Year 1 to Year 5.



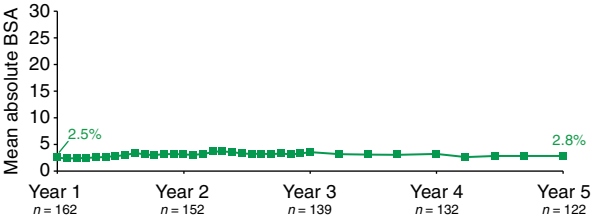
As-observed analysis with n being the number of evaluable patients; PASI, Psoriasis Area and Severity Index

Figure 6 Mean absolute PASI from Year 1 to Year 5.



BSA, body surface area; LOCF, last observation carried forward; MI, multiple imputation; n, number of evaluable patients in the as-observed analysis (the number of evaluable patients in the MI and LOCF analyses was 168 at each time point)

Figure 7 Proportion of patients with BSA affected by category from Year 1 to Year 5.



As-observed analysis with n being the number of evaluable patients; BSA, body surface area

Figure 8 Mean absolute BSA from Year 1 to Year 5.

(Figs 9 and 10, respectively). DLQI 0/1 response (indicating no impact of skin problems on patients' lives) at Year 1 was 72.7%, which was well maintained to 65.5% at Year 5. The maintenance of individual patients' DLQI through 5 years of treatment can be observed in a time-lapse video provided as Video S2. In patients with psoriatic arthritis at baseline (n = 33), 32.0% were considered HAQ-DI responders at Year 1 (improvement of at least 0.3 points from baseline, which represents minimal clinically important difference), and this sustained to 36.4% at Year 5 (Fig. 10).

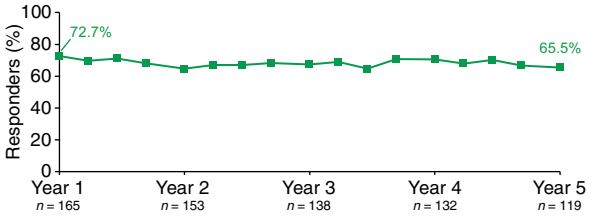
Treatment compliance

In years 4 and 5, when patients mainly self-administered therapy at home, treatment compliance (as measured by the percentage of non-missed self-administrations) was 99.5%.

Safety

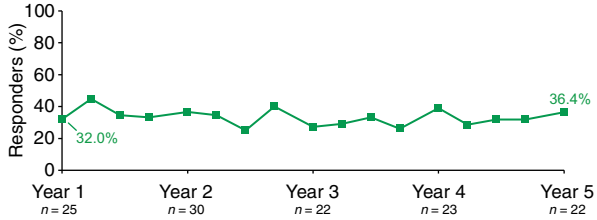
The safety profile of secukinumab 300 mg remained favourable to Year 5 with no increase in yearly AE rates from Year 1 (Table 2). The most common AEs in the overall study population, which included nasopharyngitis, back pain and headache, were consistent with those reported in the core study[7] and previous phase III studies.[8] There was one death in Year 5 due to a major adverse cardiovascular event (MACE) in a patient that had ≥2 pre-existing MACE risk factors and was not considered by the investigators to be related to study drug.

Regarding selected AEs, nine candida infections were reported through 5 years of treatment (seven vulvovaginal and two oral), but these occurred in five patients. All candidiasis occurrences were mild or moderate, and none led to study treatment discontinuation. Three cases of ulcerative colitis were reported over 5 years; one of these was an exacerbation of previously existing ulcerative colitis. The following malignancies or unspecified tumours were reported: two cases in Year 2 (one case of



As-observed analysis with n being the number of evaluable patients; DLQI 0/1, Dermatology Life Quality Index of 0 or 1 (indicating no impact of skin problems on patients' lives)

Figure 9 Percentage of patients with DLQI 0/1 response from Year 1 to Year 5.



HAQ-DI response is presented for those extension study patients that had a diagnosis of psoriatic arthritis at core study baseline (n=33)
As-observed analysis with n being the number of evaluable patients; HAQ-DI, Health Assessment Questionnaire-Disability Index

Figure 10 Percentage of patients with HAQ-DI response from Year 1 to Year 5.

Table 2 Treatment-emergent AEs by year

Treatment-emergent AEs†	Year 1 *N* = 168 168 PY *n* (IR)	Year 2 *N* = 168 162.8 PY *n* (IR)	Year 3 *N* = 157 148.8 PY *n* (IR)	Year 4 *N* = 142 136.5 PY *n* (IR)	Year 5 *N* = 134 142 PY *n* (IR)
Any AE(s)	131 (204.6)	126 (166.3)	109 (139.2)	91 (118.5)	77 (87.2)
Death	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.7)‡
Non-fatal SAEs	14 (8.8)	11 (6.9)	13 (9.1)	13 (10.1)	11 (8.0)
Most frequent AEs					
Nasopharyngitis	30 (20.1)	27 (18.1)	25 (18.8)	17 (13.5)	15 (11.1)
Hypertension	11 (6.8)	8 (5.1)	3 (2.0)	7 (5.3)	5 (3.6)
Back pain	7 (4.3)	9 (5.7)	9 (6.2)	3 (2.2)	3 (2.1)
URTI	12 (7.5)	11 (7.1)	5 (3.5)	5 (3.8)	5 (3.6)
Headache	10 (6.2)	7 (4.4)	4 (2.7)	3 (2.2)	1 (0.7)
Selected AEs					
Opportunistic infections (other than TB and candidiasis)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0)
Tuberculosis	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0)
Candida infections					
Vulvovaginal candidiasis	3 (1.8)	3 (1.9)	1 (0.7)	0 (0.0)	0 (0)
Oral candidiasis	0 (0.0)	1 (0.6)	0 (0.0)	1 (0.7)	0 (0.0)
Neutropenia	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
MACE	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.7)	1 (0.7)‡
Inflammatory bowel disease					
Crohn's disease	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Ulcerative colitis	0 (0.0)	2 (1.2)§	1 (0.7)	0 (0.0)	0 (0.0)
Malignant or unspecified tumours (excl. NMSC)	0 (0.0)	2 (1.2)¶	0 (0.0)	0 (0.0)	1 (0.7)††

†Patient exposure is calculated as a sum of individual subject durations in days divided by 365 for each interval.
‡Death was due to MACE, which was not considered by the investigators to be related to study drug; patient had ≥2 pre-existing MACE risk factors.
§Of the two cases of ulcerative colitis in Year 2, one case was an exacerbation of previously existing ulcerative colitis; the exposure-adjusted incidence rate for new-onset ulcerative colitis cases for the entire study duration (5 years) was 0.27.
¶One case of cholangiocarcinoma, one case of invasive ductal breast carcinoma.
††One case of breast cancer.
Only subjects who completed the SCULPTURE core study and continued into the extension are included in this analysis. A subject with multiple occurrences of the same AE in a one-year interval was counted only once, while a subject with multiple occurrences of the same AE in different year intervals was counted for each year.
AE, adverse event; IR, incidence rate per 100 subject-years; MACE, major adverse cardiovascular events; NMSC, non-melanoma skin cancer; PY, patient-years of exposure; SAE, serious adverse event; TB, tuberculosis; URTI, upper respiratory tract infection.

cholangiocarcinoma, one case of invasive ductal breast carcinoma), none in Year 3 or 4, and one case in Year 5 (one case of breast cancer). There were no reported opportunistic or tuberculosis infections (new or reactivations of latent tuberculosis) through 5 years of treatment.

Discussion

Most moderate-to-severe plaque psoriasis patients will require long-term treatment with biological agents to control their disease. While the short-term effects of biologics in moderate-to-severe psoriasis are well documented, studies examining long-term efficacy and safety are more limited.

Apart from secukinumab, only ustekinumab has demonstrated efficacy and safety up to 5 years of treatment for moderate-to-severe psoriasis in phase III clinical trials.[9,10] However, dose and/or dose-interval adjustments not included in the label were permitted for the overall population in these ustekinumab investigations,[9,10] and the blinded study phase extended to 52 weeks only.[9] Moreover, low and mid-potency topical corticosteroids were permitted in the long-term extension phase (from week 76).[10] In real-world evidence studies, sustained response has also been reported for ustekinumab,[11,12] but again dose and/or dose-interval adjustments were undertaken. For TNFα blockers, efficacy and safety from clinical trials have been presented over shorter time periods (3 years for adalimumab[13] and 2 years for etanercept[14]), with real-world evidence studies only, beyond this.[12,15–17] In these real-world evidence analyses, dropout rates were high, and concomitant treatments were permitted,[12,15–17] and in some instances, dose adjustments were undertaken.[12,17] For other IL-17A inhibitors, to our knowledge no phase 3 results have been published beyond 108 weeks,[18] so further long-term data are required before any sustainability conclusions can be drawn.

The present secukinumab study provides the first phase III results of an IL-17A agent demonstrating sustained efficacy and safety up to 5 years of treatment at the approved dose regimen. Apart from the secukinumab 300 mg every 4 weeks regimen (that could not be altered during the study), no use of additional therapies was permitted (except short-term use of topicals in limited body areas for up to 14 days). We can conclude, therefore, that the secukinumab efficacy results reported here are robust and without the effect of any meaningful confounders. The double-blind design was maintained for the first 3 years of treatment. Dropout rates in this long-term secukinumab study were low (comparable to previous phase 3 long-term studies),[10] only 4% (seven patients) discontinued due to a lack of efficacy (Fig. 1), and almost 100% of response rates were sustained.

Before commencing secukinumab treatment, patients had on average one-third of their body covered with psoriasis, an average PASI of 23.5 and their skin disease had a very large effect on their quality of life (mean DLQI of 13.1). Despite such severe disease, psoriasis was effectively and consistently controlled through 5 years, regardless of the efficacy response criteria and type of analysis undertaken (with or without imputation). On average, the extent and severity of psoriasis were improved by approximately 90% through 5 years. Up to three-quarters of patients also achieved high levels of response as per recently suggested treatment goals in psoriasis proposed by the National Psoriasis Foundation (BSA $\leq$1),[19] and a Canadian expert task-force (PASI $\leq$3).[20]

Efficacy reported by physicians was translated into improvements of quality of life reported by patients, including high and sustained DLQI 0/1 responses (representing no effect of skin disease on their lives) and HAQ-DI responses (representing functional improvements in patients with concomitant psoriatic arthritis) through 5 years.

The safety profile of secukinumab remained favourable through 5 years of treatment with no increase in yearly AE rates from Year 1. No new safety signals were identified, and the safety profile was consistent with that established in the secukinumab phase 2/3 clinical programme.[2,8,21,22]

High patient retention and almost 100% treatment compliance (seen during the last 2 years of treatment when patients mainly self-administered therapy at home) highlight the favourable long-term tolerability and patient satisfaction with secukinumab treatment.

A potential limitation of this study is that patients were selected by a number of inclusion and exclusion criteria when entering the SCULPTURE trial and therefore may not be representative of a real-world patient population as compared to data from registries.[23] The safety profile over a period of 5 years was favourable, but the conclusions of safety are limited by the sample size examined in this extension study (n = 168).

Over 140 000 patients have been treated with secukinumab for psoriasis or psoriatic arthritis to date since first becoming available in the clinic (Novartis 2018, data on file). This extension study demonstrates that secukinumab 300 mg delivers strong and long-lasting sustained efficacy in treating patients with moderate-to-severe plaque psoriasis through 5 years. Improvements in health-related quality of life also maintained through 5 years. These data are particularly relevant to treatment selection in psoriasis, given the potential requirement for long-term disease management.

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Supporting information

Additional Supporting Information may be found in the online version of this article:

Table S1. Percentage of patients with PASI 75/90/100 response at Year 1 and Year 5.
Table S2. Percentage of patients with mean absolute PASI responses by category at Year 1 and Year 5.
Table S3. Proportion of patients with BSA affected by category at Year 1 and Year 5.
Video S1. Time-lapse of individual patients' absolute PASI through 5 years of secukinumab treatment
Video S2. Time-lapse of individual patients' DLQI through 5 years of secukinumab treatment