Rheumatology International (2025) 45:105
https://doi.org/10.1007/s00296-025-05839-x

Rheumatology
INTERNATIONAL

CLINICAL TRIALS

High long-term retention rates of Secukinumab in psoriatic arthritis and ankylosing spondylitis: a 3-year interim analysis from the observational, prospective SERENA study, in Greek patients

Andreas Bounas[1] · Anna Kandyli[2] · Gkikas Katsifi[3] · Dimitrios Boumpa[4] · Maria G. Tektonidou[5] · Sousana Gazi[6] · Anastasios Kotrotsios[7] · Lazaros I. Sakkas[8] · Athanasios N. Georgiadis[9] · Loukas Settas[10] · Xenia Madia[11] · Dimitra Ignatiadi[11] · Petros P. Sfikakis[5]

Received: 3 October 2024 / Accepted: 19 March 2025

Abstract

SERENA is a recently completed, non-interventional, multinational, 5-year study evaluating retention, effectiveness, patient-reported outcomes and safety of secukinumab in patients with moderate-to-severe psoriasis, active psoriatic arthritis (PsA), and active ankylosing spondylitis (AS) treated in real-world settings. Three-year interim data from PsA and AS patients treated in Greek centres are presented herein. PsA and AS adults receiving secukinumab per the approved label for ≥ 16 weeks were included. Overall, 214 PsA and 81 AS eligible patients were enrolled, with mean age of 53.0 and 48.2 years and mean disease duration of 7.5 and 9.1 years, respectively. Of PsA and AS patients, 73.4% and 56.8% were bio-experienced, respectively. Secukinumab retention rates at 1, 2, and 3 years post-enrolment were 87.1%, 76.9%, and 74.0% in PsA and 89.9%, 80.5%, and 77.3% in AS patients, respectively. Main reasons for drug discontinuation were lack of effectiveness (37.1%) and adverse event (AE; 27.1%). The safety set (patients with at least 1 secukinumab dose after signing the informed consent) included 218 PsA and 81 AS patients, of whom 13.3% and 13.6% experienced secukinumab-related AEs, respectively. One malignancy was reported. No candida infections, major adverse cardiovascular events, inflammatory bowel disease or uveitis were reported. In conclusion, similarly high persistence to secukinumab was observed for both PsA and AS after 3 years of observation, with a favourable safety profile.

Keywords Effectiveness · Long-term safety · Real-world · Retention · Secukinumab · Spondyloarthritis

Introduction

Psoriatic arthritis (PsA) and ankylosing spondylitis (AS) are inflammatory rheumatic diseases within the family of spondyloarthritis (SpA) with shared clinical features [1]. The estimated prevalence of PsA and AS is 0.25% and 0.19% in Europe and 0.12% and 0,09% in Greece, respectively [2, 3]. PsA is typically characterized by peripheral joint disease, axial involvement, enthesitis, dactylitis, as well as skin and nail disease [4, 5] with the condition occurring in approximately 20% of patients with psoriasis [6]. AS primarily affects the spine and sacroiliac joints, causing chronic back pain and stiffness, while patients may also experience peripheral arthritis, enthesitis, as well as extra-articular manifestations, such as inflammatory bowel disease (IBD) and uveitis [7]. Both PsA and AS may exhibit impairments in functional status and quality of life (QoL) [8, 9].

The importance of interleukin 17 (IL- 17)-mediated immune response in the pathogenesis of both PsA and AS [10, 11] has led to the development of several biologic treatments targeting the IL- 17 pathway with demonstrated efficacy in both diseases [12]. Secukinumab is a fully human monoclonal antibody specifically targeting IL- 17 A, which has been approved by the European Medicines Agency for multiple indications including moderate-to-severe plaque psoriasis (in patients who are candidates for systemic therapy); PsA [in patients with inadequate response to previous disease modifying anti-rheumatic drugs (DMARDs)]; and, axial SpA (axSpA), referring to either active AS (radiographic axSpA) in patients with inadequate response to previous conventional therapy or active non-radiographic axSpA (nr-axSpA) in patients with objective signs of

Extended author information available on the last page of the article

Published online: 18 April 2025

inflammation, who have experienced inadequate response to non-steroidal anti-inflammatory drugs (NSAIDs) [13].

Chronic diseases like psoriasis, PsA and AS require long-term treatment, hence real-world retention rate is an important measure of sustained efficacy, long-term safety and patient satisfaction and can help guide clinical decisions [14]. Secukinumab has demonstrated sustained efficacy and safety in international clinical trials of psoriasis [15], PsA [16–24] and AS [25–28]. However, most real-world evidence (RWE) in Europe is of limited duration [29–48]. Therefore, the 5-year SERENA study aimed to provide evidence on the long-term retention, effectiveness, and safety of secukinumab in patients with the above three indications treated in a real-life clinical setting across 17 countries in Europe, Israel and Russia [49]. The study's final 5-year results are anticipated. Here, we present 3-year interim analysis results from patients with active PsA or active AS treated specifically in Greek centers.

Methods

Study design and population

SERENA (CAIN457 A3403) is a recently completed, longitudinal, observational, multinational study on the retention, effectiveness and safety of secukinumab in patients with moderate-to-severe plaque psoriasis, active PsA or active AS. The detailed study design, eligibility criteria, outcome measures and data analysis methods have been previously described [30, 49].

Briefly, adult patients with any of the above three indications were included in the study, after providing written informed consent, following secukinumab administration according to the European commission approved use. Patients should have received secukinumab for ≥ 16 weeks before enrolment. Patients with any condition preventing them from participating in the initial 2 years of observation, and those having participated or simultaneously participating in other secukinumab studies, were excluded.

Patients were followed up every 6 months until secukinumab discontinuation or study end (when all enrolled patients would have completed ≥ 2 years of follow-up or when approximately 1000 patients would have completed the 5-year final visit, whichever occurs last).

The interim analysis reported herein is restricted to patients with PsA or AS who were enrolled and observed for ≥ 3 years at centres in Greece. The target set included all patients who fulfilled the patient eligibility criteria, while the safety set included all patients who received ≥ 1 secukinumab dose after signing the informed consent. Interim 2-year analysis results of the Greek subpopulation have been previously presented at a national congress [50].

Assessments

The primary study objective was to evaluate long-term retention of secukinumab in routine clinical practice. Retention rate was assessed based on percentage of patients who had not discontinued secukinumab at specific timepoints after enrolment (i.e., after the start of observation/inclusion of patients in the study/baseline visit). Since patients were pre-treated with secukinumab at study enrolment, retention was also assessed from the start of treatment.

The following effectiveness outcome measures at 1, 2, and 3 years post enrolment were also evaluated: for PsA patients, 78 Total Joint Count (TJC) and 76 Swollen Joint Count (SJC), dactylitis, Leeds Enthesitis Index (LEI), total pain visual analogue scale (VAS), physician's global assessment (PGA) response, psoriatic nail involvement, psoriasis area and severity index (PASI); and, for AS patients, Bath AS Disease Activity Index (BASDAI), nocturnal and total back pain VAS, C-reactive protein (CRP), AS Disease Activity Score (ASDAS), patient's global assessment of disease activity using numeric rating scale, and MRI assessment of spine and/or sacroiliac joints for appearance or worsening of bone marrow edema. Impact on QoL was assessed based on patient-reported outcomes (PROs) of the health assessment questionnaire disability index (HAQ-DI) for the PsA subgroup and the functional assessment of chronic illness therapy-fatigue (FACIT-Fatigue) subscale for both PsA and AS subgroups.

Safety analysis included treatment emergent adverse events (AEs), serious AEs (SAEs) and AEs of special interest (candida infections, malignancies and major adverse cardiovascular events), as well as relationship of treatment-emergent AEs with secukinumab (hereafter mentioned as treatment-related AEs). All AEs were coded using the Medical Dictionary for Regulatory Activities (MedDRA), version 24.0.

Statistical analyses

For the estimation of retention rates, two-sided 95% Wald confidence intervals (CIs) were calculated, while Kaplan–Meier curve was utilized for the estimation of time to treatment discontinuation. Effectiveness and QoL outcome measures were analyzed based on descriptive statistics, i.e., mean and standard deviation (SD) for quantitative data, and absolute and relative frequencies for qualitative variables.

No data imputation was applied. Statistical analyses were performed using SAS® software, Version 9.4 (SAS Institute Inc., Cary, NC, USA).

Results

Patient disposition and characteristics at enrolment

Overall, 218 patients with PsA and 82 patients with AS were enrolled at Greek centres between 19 October 2017 and 29 October 2018. Four PsA patients were excluded from the target set due to protocol deviation and/or not fulfilling eligibility criteria, while one AS patient was excluded from both safety and target sets due to not receiving ≥ 1 secukinumab dose after signing informed consent. Thus, the final target and safety sets comprised of 295 (214 with PsA and 81 with AS) and 299 patients (218 with PsA and 81 with AS), respectively.

At study enrolment, 43.7% of patients were males, with the majority (96.9%) being Caucasian (Table 1). PsA patients (mean age of 53.0 years) were slightly older than AS patients (mean age of 48.2 years). A higher proportion of PsA patients had BMI ≥ 30 kg/m^2 (28.6%) compared to AS patients (13.9%), while smoking history was similar in both groups, with 39.7% of all PsA/AS patients being current or former smokers. The mean time since diagnosis was longer in AS patients (9.1 years) compared to those with PsA (7.5 years). The most frequent comorbidity in the total PsA/AS population was hypertension (19.3%), while 19.6% of PsA patients had psoriasis (Table 1).

Both study cohorts had been treated with secukinumab for a similar duration prior to enrolment (PsA: 1.1 years, AS: 0.9 years) (Table 1). The recommended dose of secukinumab for patients with PsA and AS is 150 mg (300 mg in PsA patients with moderate-to-severe plaque psoriasis or prior inadequate response to a TNF-α inhibitor), while the dose may be increased to 300 mg, based on clinical

Table 1 Sociodemographic and clinical characteristics at study enrolment

Characteristic	PsA N = 214	AS N = 81	Total N = 295
Age (years), mean ± SD (M)	53.0 ± 12.7 (214)	48.2 ± 10.7 (81)	N/A
Male, n/M (%)	91/214 (42.5)	38/81 (46.9)	129/295 (43.7)
Caucasian, n/M (%)	207/214 (96.7)	79/81 (97.5)	286/295 (96.9)
BMI (kg/m^2), mean ± SD (M)	28.3 ± 5.5 (192)	26.5 ± 4.0 (72)	N/A
BMI classification, n/M (%)			
< 25.0 kg/m^2	57/192 (29.7)	29/72 (40.3)	86/264 (32.6)
25 ≤ BMI < 30 kg/m^2	80/192 (41.7)	33/72 (45.8)	113/264 (42.8)
BMI ≥ 30 kg/m^2	55/192 (28.6)	10/72 (13.9)	65/264 (24.6)
Smoking status, n/M (%)			
Never smoker	112/190 (58.9)	49/77 (63.6)	161/267 (60.3)
Current smoker	59/190 (31.1)	22/77 (28.6)	81/267 (30.3)
Former smoker	19/190 (10.0)	6/77 (7.8)	25/267 (9.4)
Time (years) since diagnosis of PsA/AS, mean ± SD (M)	7.5 ± 6.5 (214)	9.1 ± 10.4 (81)	N/A
Duration (years) of SEC prior to enrolment, mean ± SD [range]	1.1 ± 0.6 [0.3–2.3]	0.9 ± 0.6 [0.3–2.2]	N/A
Relevant medical history/comorbidities in > 10 patients, n/M (%)			
Hypertension	47/214 (22.0)	10/81 (12.3)	57/295 (19.3)
Psoriasis	42/214 (19.6)		42/295 (14.2)
Dyslipidaemia[a]	33/214 (15.4)	7/81 (8.6)	40/295 (13.6)
Thyroid disorders[b]	20/214 (9.3)	14/81 (17.3)	34/295 (11.5)
Depression	19/214 (8.9)	5/81 (6.2)	24/295 (8.1)
Diabetes mellitus[c]	14/214 (6.5)	6/81 (7.4)	20/295 (6.8)
Fibromyalgia	10/214 (4.7)	3/81 (3.7)	13/295 (4.4)
Osteoporosis	9/214 (4.2)	2/81 (2.5)	11/295 (3.7)

[a]Including patients with dyslipidaemia, hyperlipidaemia and hypercholesterolaemia

[b]Including patients with hypothyroidism, autoimmune thyroiditis, hyperthyroidism, thyroid disorders (non-definable), thyroiditis

[c]Including patients with non-definable, type 1 and type 2 diabetes mellitus

AS ankylosing spondylitis, *BMI* body mass index, *M* number of patients with available data (i.e., with non-missing data), *N* total number of patients in the population, *n* number of patients with variable, *N/A* not applicable, *PsA* psoriatic arthritis, *SD* standard deviation, *SEC* secukinumab

response, for both indications [13]. In the PsA subgroup, most patients were receiving secukinumab 300 mg (94.4%, 202/214), while the remaining 5.6% were receiving the 150 mg dose. In contrast, in the AS subgroup, 98.8% (80/81) of patients were receiving secukinumab 150 mg and only one patient was receiving the 300 mg dose.

Of PsA and AS patients, 73.4% and 56.8%, had received treatment with biologic agents before secukinumab initiation, with 39.7% and 30.9% having received ≥ 2 prior biologics, respectively (Table 2). The reason for discontinuing prior biologics/biosimilars was lack of effectiveness in the majority of PsA (90.4%; 142/157) and AS (95.7%; 44/46) patients. In addition to biologic/biosimilar treatments, the most common documented treatments taken prior to secukinumab was DMARDs in 50.5% and 19.8% of PsA and AS patients, while 15.4% and 30.9%, respectively, had no documented prior treatments. The proportion of patients with any treatment initiated concomitantly with secukinumab was higher in PsA (37.9%) than AS patients (21.0%), with DMARDs being the most frequent in both study cohorts (Table 2).

Table 2 Treatments received before[a] and concomitant with secukinumab

Characteristic, n (%)	PsA N = 214	AS N = 81	Total N = 295
Prior treatment history with a biologic[b,c,d]			
None	57 (26.6)	35 (43.2)	92 (31.2)
1 prior biologic	72 (33.6)	21 (25.9)	93 (31.5)
2 prior biologics	37 (17.3)	14 (17.3)	51 (17.3)
≥ 3 prior biologics	48 (22.4)	11 (13.6)	59 (20.0)
Treatment regimens before secukinumab[d]			
NSAIDs	0 (0.0)	7 (8.6)	7 (2.4)
DMARDs	24 (11.2)	1 (1.2)	25 (8.5)
Biologic (or Biosimilar)	70 (32.7)	30 (37.0)	100 (33.9)
NSAIDs & DMARDs	0 (0.0)	1 (1.2)	1 (0.3)
NSAIDs, DMARDs, Biologic (or Biosimilar)	0 (0.0)	2 (2.5)	2 (0.7)
DMARDs, Biologic (or Biosimilar)	84 (39.3)	12 (14.8)	96 (32.5)
NSAIDs, Biologic (or Biosimilar)	1 (0.5)	2 (2.5)	3 (1.0)
Other	2 (0.9)	1 (1.2)	3 (1.0)
No documented	33 (15.4)	25 (30.9)	58 (19.7)
Treatment regimens concomitant with secukinumab			
NSAIDs	0 (0.0)	3 (3.7)	3 (1.0)
DMARDs	74 (34.6)	13 (16.0)	87 (29.5)
Biologic (or Biosimilar)[e]	0 (0.0)	1 (1.2)	1 (0.3)
Other	7 (3.3)	0 (0.0)	7 (2.4)
No documented	133 (62.1)	64 (79.0)	197 (66.8)

[a]All prior biologic treatments were documented without a time limit, whereas all other prior treatments were only documented if taken within 6 months prior to enrolment

[b]Among patients with PsA (N = 214), previous biologic treatments taken prior to secukinumab included adalimumab (n = 86, 40.2%), infliximab (n = 63, 29.4%), etanercept (n = 54, 25.2%), golimumab (n = 43, 20.1%), ustekinumab (n = 27, 12.6%), certolizumab (pegol) (n = 26, 12.1%) and other biologic (n = 2, 0.9%). Previous biologic treatments taken concomitantly with secukinumab included adalimumab (n = 3, 1.4%), etanercept (n = 2, 0.9%), infliximab and ustekinumab (n = 1, 0.5%, each)

[c]patients with AS (N = 81), previous biologic treatments taken prior to secukinumab included adalimumab (n = 15, 18.5%), infliximab (n = 21, 25.9%), etanercept (n = 19, 23.5%), certolizumab (pegol) (n = 15, 18.5%) and golimumab (n = 13, 16.0%). Previous biologic treatments taken concomitantly with secukinumab included adalimumab and golimumab (n = 1, 1.2%, each)

[d]In the PsA cohort, there were two patients who received prior biologic treatment, but for psoriasis indication. These have been taken into account in the "Prior treatment history with a biologic" section of this table, but not in the "Treatment regimens before secukinumab" section, where only prior biologic treatments taken for PsA are presented

[e]One patient (1.2%) initiated adalimumab concomitantly with secukinumab

AS ankylosing spondylitis, DMARDs disease-modifying antirheumatic drugs, N total number of patients in the population, n number of patients with variable, NSAIDs non-steroidal anti-inflammatory drugs, PsA psoriatic arthritis

At enrolment, 49.5% of PsA patients had tender or swollen joints, 6.1% had dactylitis, and 16.4% had enthesitis. For AS patients, the mean BASDAI score at enrolment was 3.5, and mean ASDAS-CRP score was 2.3 (Table 3).

Retention rate

Secukinumab retention rates were high after 1, 2, and 3 years after inclusion in the study, and were similar in PsA and AS patients (Fig. 1a). Time from enrolment to treatment discontinuation is displayed in Fig. 1b. Since, as per study design, secukinumab treatment had been initiated prior to study enrollment, retention rates after 1, 2, 3, and 4 years of treatment with secukinumab were also calculated and were 98.6% (N = 210; 95% CI: 96.7–100.0), 90.6% (N = 203; 95% CI: 86.4–94.9), 79.2% (N = 197; 95% CI: 73.3–85.1), and 71.0% (N = 169; 95% CI: 63.9–78.1) for PsA, and 96.3% (N = 81; 95% CI: 91.6–100.0), 88.6% (N = 79; 95% CI: 81.0–96.3), 84.4% (N = 77; 95% CI: 75.7–93.2), and 73.2% (N = 56; 95% CI: 60.7–85.7) for AS, respectively. A total of 68 patients (23.1%; 68/295) discontinued secukinumab treatment within 3 years post-enrolment, with major reasons being lack of effectiveness, followed by AE (Fig. 1c).

Effectiveness

In the PsA cohort, the proportion of patients with tender or swollen joints, dactylitis and enthesitis was reduced to 19.7%, 1.4% and 3.4% at 3 years post enrolment, respectively (Table 3). Improvements were also observed in other outcomes including mean total pain scores, mean total PASI scores, PGA 0/1 response rates, and proportion of patients with nail involvement. HAQ-DI and FACIT Fatigue scores remained stable over 3 years, with values generally reflecting minimal impact on QoL (Table 3).

In the AS cohort, mean BASDAI scores were improved, with responses sustained and further reduced from enrolment to 3 years of observation (Fig. 2a). The mean ASDAS-CRP was reduced to 1.7 mg/L at 3 years post enrolment (Table 3), with 40.9% having < 1.3 mg/L (inactive disease) compared with 15.2% at enrolment (Fig. 2b). Similar trends were observed in other outcomes, including mean nocturnal and total back pain scores (Table 3). Furthermore, and similarly to the PsA cohort, mean FACIT Fatigue scores remained stable throughout 3 years of observation. The limited sample size for AS patients at year 3 should be taken into account when interpreting the above observations (Table 3).

Table 3 Effectiveness responses with secukinumab in PsA and AS cohorts up to 3 years

Characteristic	Enrolment	Year 1	Year 2	Year 3
PsA (N = 214)				
Presence of tender or swollen joints, n/M (%)	106/214 (49.5)	41/172 (23.8)	36/140 (25.7)	14/71 (19.7)
Presence of dactylitis, n/M (%)	13/214 (6.1)	1/173 (0.6)	4/140 (2.9)	1/72 (1.4)
Presence of enthesitis, n/M (%)	21/128 (16.4)	11/123 (8.9)	5/111 (4.5)	2/58 (3.4)
Total pain (VAS 0–100), mean ± SD (M)	28.8 ± 23.0 (192)	23.1 ± 22.5 (154)	19.2 ± 20.2 (128)	15.7 ± 18.2 (63)
PGA 0/1 response, n/M (%)	109/171 (63.7)	110/153 (71.9)	96/115 (83.5)	50/62 (80.6)
Nail involvement, n/M (%)	35/214 (16.4)	15/172 (8.7)	8/140 (5.7)	3/72 (4.2)
HAQ-DI, mean ± SD (M)	0.7 ± 0.7 (167)	0.6 ± 0.6 (121)	0.6 ± 0.7 (99)	0.8 ± 0.7 (39)
FACIT Fatigue Subscale Score, mean ± SD (M)	34.6 ± 11.7 (168)	37.8 ± 11.6 (120)	39.1 ± 11.8 (99)	35.8 ± 11.8 (38)
Total PASI score, mean ± SD (M)	1.2 ± 2.2 (115)	0.9 ± 1.9 (104)	0.5 ± 1.8 (81)	0.6 ± 2.1 (32)
AS (N = 81)				
Nocturnal back pain (VAS), mean ± SD (M)	31.8 ± 23.9 (79)	26.6 ± 24.8 (66)	24.0 ± 23.0 (54)	21.2 ± 25.0 (26)
Total back pain (VAS), mean ± SD (M)	32.3 ± 22.0 (79)	29.4 ± 22.8 (66)	25.0 ± 22.6 (54)	19.8 ± 22.5 (26)
CRP > 5, n/M (%)	17/46 (37.0)	16/50 (32.0)	11/41 (26.8)	4/23 (17.4)
ASDAS-CRP, mean ± SD (M)	2.3 ± 1.0 (46)	2.1 ± 1.0 (45)	2.0 ± 1.0 (37)	1.7 ± 0.8 (22)
Patient's global assessment of disease activity (1–10 scale), mean ± SD (M)	3.9 ± 2.3 (80)	3.3 ± 2.3 (66)	3.2 ± 2.2 (52)	2.4 ± 2.4 (26)
New BME in spine or sacroiliac joint, n/M (%)	N/A	1/69 (1.4)	0/57 (0.0)	0/26 (0.0)
Worsening of pre-existing BME, n/M (%)	N/A	1/69 (1.4)	0/57 (0.0)	0/26 (0.0)
FACIT Fatigue Subscale Score, mean ± SD (M)	31.9 ± 10.4 (79)	36.1 ± 12.5 (63)	37.0 ± 11.5 (52)	35.5 ± 12.5 (24)

AS ankylosing spondylitis, *ASDAS* ankylosing spondylitis disease activity score, *BASDAI* bath ankylosing spondylitis disease activity index, *BME* bone marrow edema, *CRP* c-reactive protein, *FACIT* functional assessment of chronic illness therapy, *HAQ-DI* health assessment questionnaire disability index, *M* number of patients with available data (i.e., with non-missing data), *N* total number of patients in the population, *n* number of patients with variable, *N/A* not applicable, *PASI* psoriasis area and severity index, *PGA* physician global assessment, *PsA* psoriatic arthritis, *SD* standard deviation, *VAS* visual analogue score

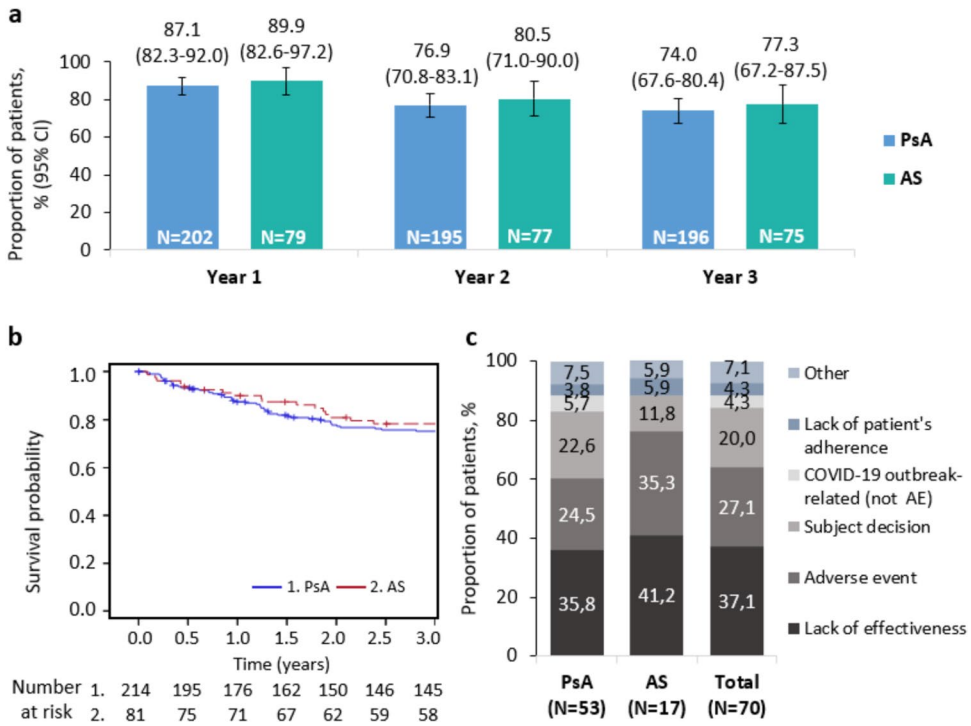

Fig. 1 Persistence to secukinumab in PsA and AS cohorts: (**a**) Retention rates at least 1, 2, and 3 years post enrolment; (**b**) Kaplan–Meier estimated time to treatment discontinuation; and, (**c**) reasons for discontinuation at 3 years post enrolment†. †Number of patients represents number of discontinuations; thus, it includes 2 patients who resumed treatment after discontinuation, before permanent discontinuation. *AS* ankylosing spondylitis, *CI* confidence interval, *IC* informed consent, *N* number of patients with available data (i.e., with non-missing data), *PsA* psoriatic arthritis

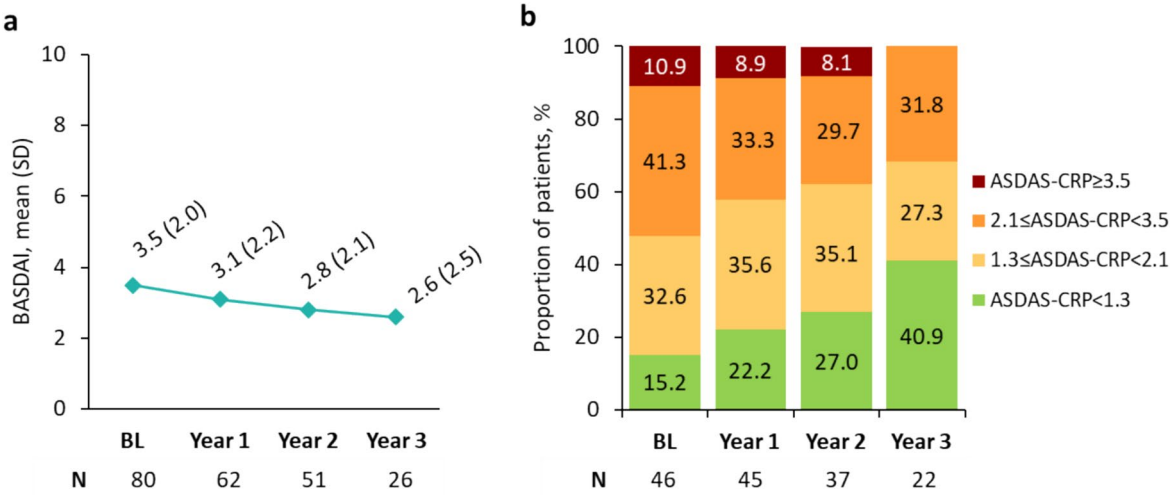

Fig. 2 Disease status based on BASDAI (**a**) and ASDAS-CRP (**b**) scores over 3 years, in the AS cohort. *AS* ankylosing spondylitis, *ASDAS* ankylosing spondylitis disease activity score, *BASDAI* bath ankylosing spondylitis disease activity index, *CRP* c-reactive protein, *N* number of patients with available data (i.e., with non-missing data), SD standard deviation

Safety

An overview of the secukinumab safety profile over 3 years of observation is provided in Table 4. At 3 years post enrolment, among patients with PsA and AS, 28.4% and 32.1% had experienced at least one AE, whereas 2.3% and 6.2% had experienced one SAE, respectively. No deaths were reported during the study observation period.

At 3 years of observation, 13.3% (29/218) of PsA patients experienced 31 treatment-related AEs, mostly comprising of drug ineffectiveness (14 of 31), followed by psoriasis/psoriatic arthropathy/arthritis (6/5/4 of 31). Among AS patients, 13.6% (11/81) experienced a treatment-related AE, mostly comprising of drug ineffectiveness (4 of 11) and AS (3 of 11). The rest of the treatment-related AEs were reported in one patient each. Of PsA and AS patients, 13.8% (30/218)

Table 4 Safety profile in PsA and AS patients during the 3-year study observation

Treatment emergent AEs	**PsA**						**AS**					
	Year 1 (N = 218)		Year 2 (N = 218)		Year 3 (N = 218)		Year 1 (N = 81)		Year 2 (N = 81)		Year 3 (N = 81)	
Number of patients with at least one AE, n (%)	37 (17.0)		57 (26.1)		62 (28.4)		17 (21.0)		25 (30.9)		26 (32.1)	
Number of patients with at least one treatment-related AE, n (%)	17 (7.8)		27 (12.4)		29 (13.3)		7 (8.6)		11 (13.6)		11 (13.6)	
Number of SAEs	6		6		8		5		8		8	
Number of patients with at least one SAE, n (%)	3 (1.4)		3 (1.4)		5 (2.3)		5 (6.2)		5 (6.2)		5 (6.2)	
Number of patients with AEs leading to discontinuation, n (%)	16 (7.3)		27 (12.4)		30 (13.8)		5 (6.2)		9 (11.1)		11 (13.6)	
Most common AEs by MedDRA SOC with IR > 2 in any subpopulation	n (%)	IR	n (%)	IR	n (%)	IR	n (%)	IR	n (%)	IR	n (%)	IR
Skin and subcutaneous tissue disorders	13 (6.0)	6.44	19 (8.7)	5.41	19 (8.7)	3.83	1 (1.2)	1.30	3 (3.7)	2.07	3 (3.7)	1.46
General disorders and administration site conditions	13 (6.0)	6.44	18 (8.3)	4.86	20 (9.2)	3.83	3 (3.7)	3.90	6 (7.4)	4.14	7 (8.6)	3.41
Musculoskeletal and connective tissue disorders	5 (2.3)	2.48	14 (6.4)	3.78	16 (7.3)	3.07	3 (3.7)	3.90	7 (8.6)	4.83	8 (9.9)	3.90
Infections and infestations	5 (2.3)	2.48	6 (2.8)	1.62	8 (3.7)	1.53	6 (7.4)	7.79	7 (8.6)	4.83	7 (8.6)	3.41
Gastrointestinal disorders		0.00	2 (0.9)	0.54	2 (0.9)	0.38	1 (1.2)	1.30	3 (3.7)	2.07	3 (3.7)	1.46
Nervous system disorders		0.00		0.00		0.00	2 (2.5)	2.60	3 (3.7)	2.76	3 (3.7)	1.95

AS ankylosing spondylitis, *AE* adverse event, *IR* incidence rate, *MedDRA* Medical Dictionary for Regulatory Activities, *N* total number of patients in the population, *n* number of patients with variable, *PsA* psoriatic arthritis, *SAE* serious adverse event, *SOC* system organ class

and 13.6% (11/81) experienced an AE leading to treatment discontinuation. Apart from one PsA patient with 'bladder transitional cell carcinoma stage II', no other AEs of special interest (candida infections, major adverse cardiovascular events) nor any events of IBD or uveitis were reported during the study for either of the two cohorts.

Discussion

The clinical value of secukinumab in the spectrum of SpA diseases is supported by many international clinical trials [16–28] and observational studies [30–48]. However, RWE on secukinumab effectiveness and safety in SpA patients in Greece is very limited [48]. Therefore, the present analysis provides valuable insight into the clinical utility of secukinumab based on comprehensive real-life data collected as part of the SERENA study from a large pool of 214 patients with PsA and 81 patients with AS treated in Greek centres.

The SERENA study describes the local population receiving secukinumab in everyday practice in terms of sociodemographic, disease and treatment characteristics, which may differ from that of randomized clinical trials that are confined by strict, and often narrow, eligibility criteria. Patients with PsA and AS in the Greek SERENA cohort had been diagnosed with the disease for a mean of 8 and 9 years, respectively, while 73.4% and 56.8% were bio-experienced with 54% of those having previously received ≥ 2 biologics, in both cohorts. Secukinumab was administered in combination with other non-biologic treatments in 37.9% of PsA patients and 19.7% of AS patients. Consistent but slightly different results were reported in a previous Greek study on 75 bio-experienced PsA patients: patients had the disease for a mean of 8 years, ≥ 65% of them were treated with ≥ 2 prior biologics, while 53% of them were treated with other non-biologic treatments concomitantly with secukinumab [48]. Small differences may be attributed to the different patient profiles and the extent of prior exposure to biologic therapies as per study design. Nevertheless, it is noted that lack of effectiveness was the major reason of prior biologics discontinuation in SERENA. Overall, data from the SERENA cohort expand on the limited local evidence, by providing a detailed picture of the population treated with secukinumab in daily clinical practice, which may contribute in healthcare decision making.

Secukinumab retention rates at 1, 2, and 3 years after study enrolment were 87.1%, 76.9%, and 74.0%, for PsA and 89.9%, 80.5%, and 77.3%, for AS patients, respectively. The results are similar to the overall SERENA cohort in which 1- and 2-year retention rates were 85% and 75% for PsA, and 86% and 79% for AS, respectively [30]. To provide a greater context in which to interpret the results, secukinumab retention rates in the SERENA PsA cohorts appear high when compared with the wide ranges reported across other European real-world cohort studies in which persistence rates of 35–82% [31–42], 20–71% [32, 35, 36, 38, 39, 43, 51], and 54–67% [33, 38] have been reported at 1, 2, and 3 years after secukinumab initiation, respectively [including data from multiple registries of the European SpA (EuroSpa) research collaboration network]. The 1- and 2-year drug survival in the prior Greek study in PsA patients was estimated at 66% and 56%, respectively [48]. Given that bio-naïve or previously untreated patients may show better persistence to secukinumab [32, 35, 37, 38, 40], this variability may be speculatively partially explained by the extent of prior exposure to biologics since all patients in the latter Greek study were bio-experienced [48].

Likewise, high retention rates were also observed in SERENA AS patients relative to other European real-world AxSpA cohorts with 1, 2 and 3 year ranges of 56–82% [33, 34, 38–40, 44–47], 35–72% [38, 39, 44, 51, 52], and 56–70% [33, 38], respectively (including EuroSpa data). The results of the current study are consistent with the pivotal clinical trials, where the proportions of patients remaining in the study at 1, 2, and ~ 3 years after treatment initiation were 80–91% [17–19, 21, 24], 76–83% [17, 20, 22, 24], and 72% [18] for PsA, and 85% [25], 78–83% [26, 28], and 86% [27] for AS, respectively (in the treatment arms corresponding to the EMA-approved dosage and mode of administration [13]).

In view of the particular study design of SERENA, it is challenging to discuss the findings in relation to the literature, since patients in SERENA (both Greek and overall cohorts) had been treated with secukinumab for a mean of 1 year prior to study inclusion [30]. In any case, 1, 2, 3 and 4 year retention rates after treatment initiation were also estimated in scope of present analysis and were 98.6%, 90.6%, 79.2% and 71.0% for PsA, and 96.3%, 88.6%, 84.4%, and 73.2% for AS, respectively, showing improved trends compared with the aforementioned outcomes calculated after inclusion in the study. Four-year retention rates were recently reported for PsA and AxSpA patients pooled from multiple European registries at 48.8% and 50.5%, respectively [51], while a 4-year retention rate of 66% was reported in a multicentric Italian PsA cohort [53]. Longer follow-up data from the SERENA study are awaited to support current findings, while investigation of variables potentially influencing secukinumab long-term retention in PsA and AS patients is warranted.

The high level of persistence to secukinumab in the current study is reinforced by the findings of sustained effectiveness and QoL outcome measures over 3 years of observation. For instance, in the SERENA cohort of AS patients treated in Greek centers, mean BASDAI and ASDAS-CRP was ≤ 3.5 and ≤ 2.3, respectively, throughout

the observation period of this 3-year interim analysis, corroborating prior EuroSpA data of 3.9 and 2.5 at year 1 after treatment initiation [46]. Mean HAQ-DI in PsA patients was < 1 from enrolment onwards, supporting HAQ-DI results of the FUTURE- 1 trial [16] and HAQ-S results of another prospective RWE study in Italy [43]. In addition, favorable outcomes were reported on the FACIT-Fatigue scale in SERENA, with mean scores of 36–38 from year 1 onwards in both PsA and AS Greek cohorts of SERENA. These values are not much inferior to the mean score of 44 which is derived from a nationally representative sample of the German general population [54]. Overall, the above observations extend the existing findings of sustained improvement in disease activity, symptoms and functional ability with continued secukinumab treatment.

Biologic therapies such as secukinumab are intended for long-term use in chronic diseases. Therefore, when making treatment decisions for managing diseases in the SpA spectrum, it is important to consider the long-term safety of available therapies. In the SERENA Greek cohort of PsA and AS patients, no unexpected AEs were detected over 3 years of observation. The most common reason for secukinumab discontinuation was lack of effectiveness, which is in line with 2-year interim results of the overall SERENA cohort [30] and prior observational studies [31–34, 36, 38–47], including the prior Greek study on PsA bio-experienced patients [48]. Safety data presented herein support that secukinumab is well-tolerated in the real world, and further confirm that special interest AEs, IBD and uveitis are uncommon in secukinumab-treated PsA and AS patients.

The limitations of the SERENA observational study have been described extensively elsewhere [30, 49]. The most important limitation pertains to patient selection bias arising from the fact that patients were treated with secukinumab for ≥ 16 weeks prior to study enrolment. This may have led to potential overestimation of long-term retention as well as perceived effectiveness, as it may have excluded those discontinuing the drug earlier due to AEs/lack of efficacy (survivorship bias), and may have enriched for those more responsive, adherent and/or healthier (healthy adherer effect). As a result, our findings are possibly more generalizable to a population with responsive disease and steadier healthcare touchpoints. The above sources of bias should be taken into consideration when interpreting the comparisons between our results and previously published data on secukinumab persistence. Furthermore, given that effectiveness and QoL outcome measures were not part of the primary study objectives, the findings of certain long follow-up visits were derived from small sample sizes, thus should be interpreted with caution (e.g. size of 58–72 PsA patients and 22–26 AS patients for effectiveness outcomes at year 3; 32–39 PsA patients and 24 AS patients for PROs at year 3). Lastly, with regard to comorbidities, it is worth noting that their documentation was based on patient claims at baseline and not on investigators' clinical judgment or another specialist's diagnosis, implying that their percentages in present analysis could be not indicative of PsA and AS populations' characteristics overall.

In conclusion, this 3-year interim analysis of real-world data from Greece showed high long-term retention for secukinumab, with similar trends for patients with active PsA and AS, accompanied by sustained effectiveness and QoL outcome measures. Safety data collected for up to 3 years confirmed the long-term favorable safety profile of secukinumab in the real-world setting without any new signals arising. These outcomes enrich Greek real-world evidence of secukinumab in PsA and AS and strengthen emerging data from other European observational studies, altogether supporting the clinical utility of secukinumab in these diseases.

Ethics approval

All patients provided written informed consent before study enrolment. The study is conducted in accordance with Good Clinical Practice (GCP), the Guidelines for Good Pharmacoepidemiology Practices (GPP) of the International Society for Pharmacoepidemiology (ISPE 2008), the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guidelines, the Declaration of Helsinki and all local regulations. Approval by National Ethics Committee is not applicable for non-interventional studies in Greece. In accordance with local regulations, the study was approved by independent ethics committees or institutional review boards of each participating center, i.e., General Hospital of Patra O AGIOS ANDREAS Rheumatology Clinic (ΑΠ 48/20.07.2017), Euromedica General Clinic of Thessaloniki Rheumatology department (ΑΠ 577/26.07.2017 and ΑΠ 787/11.07.2018), General Hospital of Attiki KAT (9782/01.08.2017), General Hospital of Athens Laiko Main Centre (ΑΠ 1002/11.09.2017), University General Hospital of Larissa Rheumatology Clinic (44,729/28.09.2017), Euromedica Kyanous Stavros Rheumatologic Unit (05.10.2017), Navy Hospital of Athens NNA Rheumatology Clinic (ΑΠ 7/17 09.10.2017), University General Hospital of Ioannina Main Centre (17/12.10.2017), Hospital Center ERRIKOS NTYNAN (09.11.2017), General Hospital of Athens Laiko 1 st Dept Propaedeutic Medicine (15,468/11.11.2017), General Clinic of Patra OLYMPION (14.11.2017), University General Hospital of Heraklion Rheumatology Clinic (31/15.11.2017), University General Hospital ATTIKON (17 th meeting/18.11.2017), University Hospital of Athens Ippokrateio 2nd department of Internal Medicine

(48/22.11.2017), General Hospital of Thessaloniki IPPOKRATEIO Main Centre (919/18.01.2018).

Acknowledgements The authors wish to thank Optimapharm Greece, for medical writing support, which was funded by Novartis (Hellas) S.A.C.I. There was no use of AI for writing and editing of the article.

Author contributions A Bounas, A Kandyli, G Katsifis, D Boumpas, MG Tektonidou, S Gazi, A Kotrotsios, LI Sakkas, AN Georgiadis, and L Settas were involved in the acquisition of data, D Ignatiadi was involved in the conception/design of work, X. Madia was involved in the conception/design of work, analysis/interpretation of data, as well as drafting the manuscript, while PP Sfikakis contributed to the trial's scientific integrity and was involved in the interpretation of data. All authors were responsible for critically revising the work for important intellectual content and for making all content and editorial decisions. All authors had final approval of the manuscript version to be published and are accountable for all aspects of the work in ensuring the accuracy and integrity of this manuscript.

Funding This work was sponsored by Novartis Hellas S.A.C.I. The sponsor was involved in all stages of the study, from design to manuscript preparation, including funding of open access publishing.

Data availability Open Data Sharing is available upon reasonable request. The data sets generated and/or analyzed during the current study are not publicly available. Novartis is committed to sharing with qualified external researchers' access to patient-level data and supporting clinical documents from eligible studies. These requests are reviewed and approved on the basis of scientific merit. All data provided are anonymized to respect the privacy of patients who have participated in the study in line with applicable laws and regulations. The data may be requested by writing to the corresponding author. No part of this manuscript, including the text and graphics, are copied, or published elsewhere in whole or in part. Interim 2-year analysis results have been previously presented at the 28 th Panhellenic Rheumatology Congress (Bounas A, Theodoridou A, Kandili A, et al.; 2022; AA073).

Declarations

Conflicts of interest A. Bounas: research grants, honorarium for educational activities and consultancy fees from Abbvie, Aenorasis, Amgen, Bausch Health, FARAN, Genesis Pharma, GSK, Janssen, MSD, Novartis, Pfizer, UCB; A. Kandyli: clinical trial investigator fees, honorarium for educational activities and consultancy fees from Vianex, Enorasis, Abbvie, Pfizer, UCB and SOBI; G. Katsifis: honorarium for educational activities and consultancy fees from Abbvie, Boehringer Ingelheim, Janssen, Galapagos, Genesis Pharma, MSD, Novartis, Pfizer and Viatris; D. Boumpas: clinical trial investigator fees, honorarium for educational activities and consultancy fees from Abbvie, AstraZeneca, GSK, Novartis, Enorasis and Lilly; M. G. Tektonidou: research grants, honorarium for educational activities and consultancy fees from GSK, UCB and Lilly; S. Gazi: clinical trial investigator fees, honorarium for educational activities and consultancy fees from Pfizer, Lilly, Faran, Elpen, Abbvie and UCB; A. Kotrotsios: clinical trial investigator fees and honorarium for educational activities from Vianex, Novartis, UCB, Amgen, Pfizer and Abbvie; L. I. Sakkas: congress support from Abbvie; A. N. Georgiadis: clinical trial investigator fees, honorarium for educational activities and consultancy fees from Faran and Aenorasis; L. Settas: clinical trial investigator fees, honorarium for educational activities and consultancy fees from PPD, Pfizer, Abbvie, Horizon, Faran, Amgen and Sanofi; X. Madia: employee of Novartis Hellas S.A.C.I.; D. Ignatiadi: employee of Novartis Hellas S.A.C.I.; P. P. Sfikakis: research grants and consultancy fees from Abbvie, Roche, Pfizer, Faran, Amgen, Janssen, Boehringer Ingelheim, Gilead, Actelion, Genesis Pharma, MSD, UCB, Enorasis, Lilly and Novartis.

References

1. Arthritis Foundation. The Spondyloarthritis Family. https://www.arthritis.org/diseases/spondyloarthritis. Accessed December 2024.
2. Stolwijk C, van Onna M, Boonen A, van Tubergen A (2016) Global prevalence of spondyloarthritis: a systematic review and meta-regression analysis. Arthritis Care Res 68:1320–1331. https://doi.org/10.1002/acr.22831
3. Anagnostopoulos I, Zinzaras E, Alexiou I, Papathanasiou AA, Davas E, Koutroumpas A et al (2010) The prevalence of rheumatic diseases in central Greece: a population survey. BMC Musculoskelet Disord 11:98. https://doi.org/10.1186/1471-2474-11-98
4. Coates LC, Helliwell PS (2017) Psoriatic arthritis: state of the art review. Clin Med 17:65–70. https://doi.org/10.7861/clinmedicine.17-1-65
5. Ritchlin CT, Colbert RA, Gladman DD (2017) Psoriatic arthritis. N Engl J Med 376:957–970. https://doi.org/10.1056/NEJMra1505557
6. Alinaghi F, Calov M, Kristensen LE, Gladman DD, Coates LC, Jullien D et al (2019) Prevalence of psoriatic arthritis in patients with psoriasis: a systematic review and meta-analysis of observational and clinical studies. J Am Acad Dermatol 80:251–65.e19. https://doi.org/10.1016/j.jaad.2018.06.027
7. Taurog JD, Chhabra A, Colbert RA (2016) Ankylosing Spondylitis and Axial Spondyloarthritis. N Engl J Med 375:1303. https://doi.org/10.1056/NEJMc1609622

8. Walsh JA, Ogdie A, Michaud K, Peterson S, Holdsworth EA, Karyekar CS et al (2023) Impact of key manifestations of psoriatic arthritis on patient quality of life, functional status, and work productivity: Findings from a real-world study in the United States and Europe. Joint Bone Spine 90:105534. https://doi.org/10.1016/j.jbspin.2023.105534
9. Kotsis K, Voulgari PV, Drosos AA, Carvalho AF, Hyphantis T (2014) Health-related quality of life in patients with ankylosing spondylitis: a comprehensive review. Expert Rev Pharmacoecon Outcomes Res 14:857–872. https://doi.org/10.1586/14737167.2014.957679
10. Blauvelt A, Chiricozzi A (2018) The immunologic role of IL-17 in psoriasis and psoriatic arthritis pathogenesis. Clin Rev Allergy Immunol 55:379–390. https://doi.org/10.1007/s12016-018-8702-3
11. Tam HKJ, Robinson PC, Nash P (2022) Inhibiting IL-17A and IL-17F in rheumatic disease: therapeutics help to elucidate disease mechanisms. Curr Rheumatol Rep 24:310–320. https://doi.org/10.1007/s11926-022-01084-4
12. He C, Xue C, Zhu G, Kang P (2021) Efficacy and safety of interleukin-17 inhibitors in the treatment of chronic rheumatic diseases: A combined and updated meta-analysis. J Clin Pharm Ther 46:895–906. https://doi.org/10.1111/jcpt.13416
13. European Medicines Agency Cosentyx : EPAR - Product Information. https://www.ema.europa.eu/en/documents/product-information/cosentyx-epar-product-information_en.pdf. Accessed December 2024.
14. van den Reek J, Kievit W, Gniadecki R, Goeman JJ, Zweegers J, van de Kerkhof PCM et al (2015) Drug survival studies in dermatology: principles, purposes, and pitfalls. J Invest Dermatol 135:1–5. https://doi.org/10.1038/jid.2015.171
15. Berg SH, Balogh EA, Ghamrawi RI, Feldman SR (2021) A review of secukinumab in psoriasis treatment. Immunotherapy 13:201–216. https://doi.org/10.2217/imt-2020-0195
16. Mease PJ, Kavanaugh A, Reimold A, Tahir H, Rech J, Hall S et al (2020) Secukinumab provides sustained improvements in the signs and symptoms of psoriatic arthritis: final 5-year results from the phase 3 FUTURE 1 study. ACR Open Rheumatol 2:18–25. https://doi.org/10.1002/acr2.11097
17. McInnes IB, Mease PJ, Ritchlin CT, Rahman P, Gottlieb AB, Kirkham B et al (2017) Secukinumab sustains improvement in signs and symptoms of psoriatic arthritis: 2 year results from the phase 3 FUTURE 2 study. Rheumatology 56:1993–2003. https://doi.org/10.1093/rheumatology/kex301
18. Nash P, McInnes IB, Rahman P, Gottlieb AB, Kirkham B, Ding K, et al. (2018) THU0322 Secukinumab provides sustained improvements in the signs and symptoms of active psoriatic arthritis: 3-year results from the phase 3 future 2 study. Annals of the Rheumatic Diseases 77:379. https://doi.org/10.1136/annrheumdis-2018-eular.2379
19. Nash P, Mease PJ, McInnes IB, Rahman P, Ritchlin CT, Blanco R et al (2018) Efficacy and safety of secukinumab administration by autoinjector in patients with psoriatic arthritis: results from a randomized, placebo-controlled trial (FUTURE 3). Arthritis Res Ther 20:47. https://doi.org/10.1186/s13075-018-1551-x
20. Kivitz AJ, Nash P, Tahir H, Everding A, Mann H, Kaszuba A et al (2019) Efficacy and safety of subcutaneous Secukinumab 150 mg with or without loading regimen in Psoriatic Arthritis: results from the FUTURE 4 study. Rheumatol Ther 6:393–407. https://doi.org/10.1007/s40744-019-0163-5
21. van der Heijde D, Mease PJ, Landewé RBM, Rahman P, Tahir H, Singhal A et al (2019) Secukinumab provides sustained low rates of radiographic progression in psoriatic arthritis: 52-week results from a phase 3 study, FUTURE 5. Rheumatology 59:1325–1334. https://doi.org/10.1093/rheumatology/kez420
22. Mease PJ, Landewé R, Rahman P, Tahir H, Singhal A, Boettcher E et al (2021) Secukinumab provides sustained improvement in signs and symptoms and low radiographic progression in patients with psoriatic arthritis: 2-year (end-of-study) results from the FUTURE 5 study. RMD Open 7:e001600. https://doi.org/10.1136/rmdopen-2021-001600
23. McInnes IB, Behrens F, Mease PJ, Kavanaugh A, Ritchlin C, Nash P et al (2020) Secukinumab versus adalimumab for treatment of active psoriatic arthritis (EXCEED): a double-blind, parallel-group, randomised, active-controlled, phase 3b trial. Lancet 395:1496–1505. https://doi.org/10.1016/s0140-6736(20)30564-x
24. Kavanaugh A, Mease PJ, Reimold AM, Tahir H, Rech J, Hall S et al (2017) Secukinumab for long-term treatment of psoriatic arthritis: a two-year followup from a phase iii, randomized, double-blind placebo-controlled study. Arthritis Care Res 69:347–355. https://doi.org/10.1002/acr.23111
25. Baeten D, Sieper J, Braun J, Baraliakos X, Dougados M, Emery P et al (2015) Secukinumab, an Interleukin-17A Inhibitor, in Ankylosing Spondylitis. N Engl J Med 373:2534–2548. https://doi.org/10.1056/NEJMoa1505066
26. Braun J, Baraliakos X, Deodhar A, Baeten D, Sieper J, Emery P et al (2017) Effect of secukinumab on clinical and radiographic outcomes in ankylosing spondylitis: 2-year results from the randomised phase III MEASURE 1 study. Ann Rheum Dis 76:1070–1077. https://doi.org/10.1136/annrheumdis-2016-209730
27. Marzo-Ortega H, Sieper J, Kivitz A, Blanco R, Cohen M, Delicha EM et al (2017) Secukinumab provides sustained improvements in the signs and symptoms of active ankylosing spondylitis with high retention rate: 3-year results from the phase III trial, MEASURE 2. RMD Open 3:e000592. https://doi.org/10.1136/rmdopen-2017-000592
28. Kivitz AJ, Wagner U, Dokoupilova E, Supronik J, Martin R, Talloczy Z et al (2018) Efficacy and safety of Secukinumab 150 mg with and without loading regimen in ankylosing spondylitis: 104-week results from MEASURE 4 study. Rheumatology and therapy 5:447–462. https://doi.org/10.1007/s40744-018-0123-5
29. Augustin M, Jullien D, Martin A, Peralta C (2020) Real-world evidence of secukinumab in psoriasis treatment - a meta-analysis of 43 studies. J Eur Acad Dermatol Venereol 34:1174–1185. https://doi.org/10.1111/jdv.16180
30. Kiltz U, Sfikakis PP, Gaffney K, Bounas A, Gullick N, Lespessailles E et al (2022) Interim 2-year analysis from SERENA: a real-world study in patients with psoriatic arthritis or ankylosing spondylitis treated with secukinumab. Rheumatol Ther 9:1129–1142. https://doi.org/10.1007/s40744-022-00460-x
31. Lindström U, Glintborg B, Di Giuseppe D, Schjødt Jørgensen T, Gudbjornsson B, Lederballe Grøn K et al (2021) Comparison of treatment retention and response to secukinumab versus tumour necrosis factor inhibitors in psoriatic arthritis. Rheumatology 60:3635–3645. https://doi.org/10.1093/rheumatology/keaa825
32. Alegre-Sancho JJ, Núñez-Monje V, Campos-Fernández C, Balaguer-Trull I, Robustillo-Villarino M, Aguilar-Zamora M, et al. (2023) Real-world effectiveness and persistence of secukinumab in the treatment of patients with psoriatic arthritis. Front Med 10:1294247. https://doi.org/10.3389/fmed.2023.1294247
33. Favalli E, Marchesoni A, Balduzzi S, Montecucco C, Lomater C, Crepaldi G, et al. (2020) FRI0273 EFFECTIVENESS AND RETENTION RATE OF SECUKINUMAB FOR PSORIATIC ARTHRITIS AND AXIAL SPONDYLOARTHRITIS: REAL-LIFE DATA FROM THE ITALIAN LORHEN REGISTRY. Ann Rheumat Dis 79:722.1–3. https://doi.org/10.1136/annrheumdis-2020-eular.3197
34. García-Dorta A, León-Suarez P, Peña S, Hernández-Díaz M, Rodríguez-Lozano C, González-Dávila E, et al. (2022) Association of gender, diagnosis, and obesity with retention rate of Secukinumab in Spondyloarthropathies: results form a multicenter real-world study. Front Med 8: 815881. https://doi.org/10.3389/fmed.2021.815881

35. Geale K, Lindberg I, Paulsson EC, Wennerström ECM, Tjärnlund A, Noel W, et al. (2020) Persistence of biologic treatments in psoriatic arthritis: a population-based study in Sweden. Rheumatol Adv Pract 4:rkaa070. https://doi.org/10.1093/rap/rkaa070
36. Letarouilly JG, Flachaire B, Labadie C, Kyheng M, Cohen N, Sellam J et al (2021) Secukinumab and ustekinumab treatment in psoriatic arthritis: results of a direct comparison. Rheumatology 60:2773–2782. https://doi.org/10.1093/rheumatology/keaa710
37. Michelsen B, Georgiadis S, Di Giuseppe D, Loft AG, Nissen MJ, Iannone F et al (2022) Real-world six- and twelve-month drug retention, remission, and response rates of Secukinumab in 2,017 patients with psoriatic arthritis in thirteen european countries. Arthritis Care Res 74:1205–1218. https://doi.org/10.1002/acr.24560
38. Moreno-Ramos MJ, Sanchez-Piedra C, Martínez-González O, Rodríguez-Lozano C, Pérez-Garcia C, Freire M et al (2022) Real-world effectiveness and treatment retention of secukinumab in patients with psoriatic arthritis and axial spondyloarthritis: a descriptive observational analysis of the spanish BIOBADASER registry. Rheumatol Ther 9:1031–1047. https://doi.org/10.1007/s40744-022-00446-9
39. Alonso S, Villa I, Fernández S, Martín JL, Charca L, Pino M, et al. (2021) Multicenter study of Secukinumab survival and safety in spondyloarthritis and psoriatic arthritis: SEcukinumab in Cantabria and ASTURias Study. Front Med 8:679009. https://doi.org/10.3389/fmed.2021.679009
40. Kiltz U, Peterlik D, Winkelmann V, Tony H-P, on behalf of the aQUILA Study Group. AB0705 AQUILA STUDY IN GERMANY – REAL WORLD ADHERENCE AND PERSISTENCE OF SECUKINUMAB TREATMENT IN ANKYLOSING SPONDYLITIS AND PSORIATIC ARTHRITIS PATIENTS – AN INTERIM ANALYSIS. Ann Rheumat Dis 2019;78:1814–1815.
41. Martinis F, Caimmi C, Foti R, Visalli E, Amato G, Ramonda R, et al. AB0761 SECUKINUMAB FOR THE TREATMENT OF PSORIATIC ARTHRITIS IN REAL LIFE: AN ITALIAN EXPERIENCE. Ann Rheumatic Dis 2019;78:1848.
42. Chimenti MS, Fonti GL, Conigliaro P, Sunzini F, Scrivo R, Navarini L et al (2020) One-year effectiveness, retention rate, and safety of secukinumab in ankylosing spondylitis and psoriatic arthritis: a real-life multicenter study. Exp Opin Biol Ther 20:813–821. https://doi.org/10.1080/14712598.2020.1761957
43. Ramonda R, Lorenzin M, Carriero A, Chimenti MS, Scarpa R, Marchesoni A, et al. (2021) Effectiveness and safety of secukinumab in 608 patients with psoriatic arthritis in real life: a 24-month prospective, multicentre study. RMD Open 7:e001519. https://doi.org/10.1136/rmdopen-2020-001519
44. Sivera F, Núñez-Monje V, Campos-Fernández C, Balaguer-Trull I, Robustillo-Villarino M, Aguilar-Zamora M, et al. (2023) Real-world experience with secukinumab in the entire axial spondyloarthritis spectrum. Front Med 10. https://doi.org/10.3389/fmed.2023.1156557
45. Dougados M, Lucas J, Desfleurs E, Claudepierre P, Goupille P, Ruyssen-Witrand A, et al. (2023) Factors associated with the retention of secukinumab in patients with axial spondyloarthritis in real-world practice: results from a retrospective study (FORSYA). RMD Open 9. https://doi.org/10.1136/rmdopen-2022-002802
46. Michelsen B, Lindström U, Codreanu C, Ciurea A, Zavada J, Loft AG, et al. (2020) Drug retention, inactive disease and response rates in 1860 patients with axial spondyloarthritis initiating secukinumab treatment: routine care data from 13 registries in the EuroSpA collaboration. RMD Open 6. https://doi.org/10.1136/rmdopen-2020-001280
47. Glintborg B, Lindström U, Giuseppe DD, Provan SA, Gudbjornsson B, Hetland ML et al (2022) One-year treatment outcomes of secukinumab versus tumor necrosis factor inhibitors in spondyloarthritis: results from five nordic biologic registries including more than 10,000 treatment courses. Arthritis Care Res (Hoboken) 74:748–758. https://doi.org/10.1002/acr.24523
48. Klavdianou K, Lazarini A, Grivas A, Tseronis D, Tsalapaki C, Rapsomaniki P et al (2020) Real life efficacy and safety of secukinumab in biologic-experienced patients with psoriatic arthritis. Front Med 7:288. https://doi.org/10.3389/fmed.2020.00288
49. Kiltz U, Sfikakis PP, Gaffney K, Sator PG, von Kiedrowski R, Bounas A et al (2020) Secukinumab use in patients with moderate to severe psoriasis, psoriatic arthritis and ankylosing spondylitis in real-world setting in europe: baseline data from SERENA study. Adv Ther 37:2865–2883. https://doi.org/10.1007/s12325-020-01352-8
50. Bounas A, Theodoridou A, Kandili A, Boumpas D, Katsifis G, Gazi S, et al. (2022) AA073 - ΕΝΔΙΑΜΕΣΗ ΔΙΕΤΗΣ ΑΝΑΛΥΣΗ ΤΗΣ ΜΕΛΕΤΗΣ SERENA: ΜΙΑ ΜΕΛΕΤΗ ΠΑΡΑΤΗΡΗΣΗΣ ΣΕ ΕΛΛΗΝΕΣ ΑΣΘΕΝΕΙΣ ΜΕ ΨΩΡΙΑΣΙΚΗ ΑΡΘΡΙΤΙΔΑ ΚΑΙ ΑΓΚΥΛΟΠΟΙΗΤΙΚΗ ΣΠΟΝΔΥΛΑΡΘΡΙΤΙΔΑ ΠΟΥ ΕΛΑΒΑΝ ΘΕΡΑΠΕΙΑ ΜΕ ΣΕΚΟΥΚΙΝΟΥΜΑΜΠΗ ΣΤΗΝ ΚΑΘΗΜΕΡΙΝΗ ΚΛΙΝΙΚΗ ΠΡΑΚΤΙΚΗ. 28th Panhellenic Rheumatology Congress Abstracts. Available at: https://ere.gr/assets/files/synedria/panellinio_2022/28o-RHEUMATOLOGY_FINAL-Program-v3.pdf. Accessed December 2024.
51. Pons M, Georgiadis S, Østergaard M, Ahmadzay ZF, Glintborg B, Heberg J, et al. (2024) Four-year secukinumab treatment outcomes in European real-world patients with axial spondyloarthritis and psoriatic arthritis. Joint Bone Spine : 105824. https://doi.org/10.1016/j.jbspin.2024.105824
52. Gentileschi S, Cannistrà C, Gaggiano C, Damiani A, Carli L, Benucci M, et al. (2024) Secukinumab for the treatment of axial spondyloarthritis: long-term real-life data from five italian referral centers. J Personalized Med 14. https://doi.org/10.3390/jpm14111105
53. Ramonda R, Lorenzin M, Chimenti MS, Atzeni F, Semeraro A, D'Angelo S et al (2024) Four-year effectiveness, safety and drug retention rate of secukinumab in psoriatic arthritis: a real-life Italian multicenter cohort. Arthritis Res Ther 26:172. https://doi.org/10.1186/s13075-024-03401-x
54. Montan I, Löwe B, Cella D, Mehnert A, Hinz A (2018) General population norms for the functional assessment of chronic illness therapy (FACIT)-fatigue scale. Value Health 21:1313–1321. https://doi.org/10.1016/j.jval.2018.03.013

Authors and Affiliations

Andreas Bounas[1] · Anna Kandyli[2] · Gkikas Katsifi[3] · Dimitrios Boumpa[4] · Maria G. Tektonidou[5] · Sousana Gazi[6] · Anastasios Kotrotsios[7] · Lazaros I. Sakkas[8] · Athanasios N. Georgiadis[9] · Loukas Settas[10] · Xenia Madia[11] · Dimitra Ignatiadi[11] · Petros P. Sfikakis[5]

✉ Dimitra Ignatiadi
dimitra.ignatiadi@novartis.com

Andreas Bounas
andbounas@gmail.com

Anna Kandyli
annakandili@yahoo.gr

Gkikas Katsifi
katsifisg@yahoo.gr

Dimitrios Boumpa
boumpasd@uoc.gr

Maria G. Tektonidou
mtektonidou@gmail.com

Sousana Gazi
susanagazi@yahoo.com

Anastasios Kotrotsios
kotrotsiostasos@hotmail.gr

Lazaros I. Sakkas
lsakkas@uth.gr

Athanasios N. Georgiadis
athangeorgiadis@yahoo.gr

Loukas Settas
loukassettas@gmail.com

Xenia Madia
xanthi-xanthippi.madia@novartis.com

Petros P. Sfikakis
psfikakis@med.uoa.gr

[1] "OLYMPION", General Clinic of Patra, Patra, Greece

[2] Private Practice, Athens, Greece

[3] Rheumatology Clinic, Naval Hospital of Athens, Athens, Greece

[4] Rheumatology and Clinical Immunology Unit, 4th Department of Internal Medicine, Joint Rheumatology Program, Attikon University Hospital, National and Kapodistrian University of Athens Medical School, Athens, Greece

[5] First Department of Propaedeutic and Internal Medicine, Medical School, Joint Academic Rheumatology Program, National and Kapodistrian University of Athens, Athens, Greece

[6] Department of Rheumatology, "KAT" General Hospital of Attica, Athens, Greece

[7] Department of Public and One Health, School of Health Sciences, University of Thessaly, Larissa, Greece

[8] Department of Rheumatology and Clinical Immunology, Faculty of Medicine, School of Health Sciences, University of Thessaly, Larissa, Greece

[9] Private Practice, Ioannina, Greece

[10] University of Thessaloniki, Thessaloniki, Greece

[11] Novartis Hellas S.A.C.I., Athens, Greece