

CAIN457ATH02 Study Results Abstract for Public Disclosure

Title

2 Years Prospective study to collect Real-life data On the retention, quality of life, effectiveness and treatment pattern of secukinumab in adult patients with Moderate to severe plaque psoriasis, Psoriatic arthritis, ankylosing spondylitis and non-radiographic axial spondyloarthritis (PROMPT)

Date

13 July 2026

NIS Type

NIS with Primary Data Collection

Novartis Drug NIS

Keywords

Ankylosing Spondylitis, Psoriasis, Psoriatic Arthritis, Real-world, Secukinumab, Thailand

Rationale and background

Secukinumab has been approved for the treatment of moderate to severe plaque type psoriasis, PsA, AS and non-radiographic axial SpA in adults. In the pivotal clinical studies, secukinumab showed good efficacy and tolerability profiles; however, information on its use under real-life conditions in Thailand is sparse. This study aims to evaluate the retention, quality of life (QoL), effectiveness, and treatment pattern of secukinumab in patients with moderate to severe plaque psoriasis, active PsA, active AS and active non-radiographic axial SpA who receive secukinumab in real world practice and its impact on work or school absenteeism. The study is designed to be prospective data collection in order to gain information on QoL which is not routinely recorded in the daily practice.

Research question and objectives

Primary objective

To assess the 2 year retention of secukinumab treatment in routine clinical practice for the treatment of moderate to severe plaque-type psoriasis, active PsA, active AS and active non-radiographic axial SpA (overall) based on the first dose of secukinumab administered since the start of the study.

Secondary objectives

All indications

- To assess 2 year retention of secukinumab treatment in routine clinical practice for the treatment of each individual indication (i.e. moderate to severe plaque-type psoriasis, active PsA, active AS or non-radiographic axial SpA) based on the first dose of secukinumab administered since the start of the study.
- To identify factors affecting the retention of secukinumab treatment in each indication.
- To describe QoL of the patients of each indication during study period by using Euro-QoL-5 dimension questionnaire (EQ-5D).
- To describe the treatment pattern with secukinumab for the treatment of moderate to severe plaque psoriasis, active PsA, active AS and active non-radiographic axial SpA in terms of dosing and administration intervals during study period.

- To describe work/school absenteeism change to the treating condition during the 2 years follow up period.

Psoriasis

- To describe 2 year effectiveness of secukinumab in routine clinical practice for the treatment of moderate to severe plaque psoriasis as observed over the study duration.
- To describe 2 year QoL, which will be evaluated based on patient-reported outcomes (PROs) instruments used for patients with psoriasis, such as the Dermatology Life Quality Index (DLQI).
- To assess correlation between effectiveness of secukinumab and QoL in psoriasis.

Psoriatic arthritis

- To describe 2 year effectiveness of secukinumab in routine clinical practice for the treatment of active PsA as observed over the study duration.
- To describe 2 year QoL, which will be evaluated based on PROs instruments used for patients with PsA, such as the Health Assessment Questionnaire-Disability Index (HAQ-DI) and the Functional Assessment of Chronic Illness Therapy – Fatigue (FACIT-Fatigue).
- To assess correlation between effectiveness of secukinumab and QoL in PsA.

Ankylosing spondylitis and non-radiographic axial SpA

- To describe 2 year effectiveness of secukinumab in routine clinical practice for the treatment of active AS as observed over the study duration.
- To describe 2 year QoL, which will be evaluated based on PROs instrument routinely used for patients with AS and non-radiographic axial SpA, such as FACIT-Fatigue.
- To assess correlation between effectiveness of secukinumab and QoL in AS.

Study design

This is a prospective observational study.

Setting

This study has been performed at 13 dermatologic centers in Thailand. Data collection will be done at baseline (enrollment date) and every 6 +/- 2 months until 24 months visit is completed or the patient chooses to exit the study.

Subjects and study size, including dropouts

All eligible patients visiting study sites from the study start date until enrollment are chronologically enrolled into the study. The approximate study size is 360 for all indications in total.

Individual patients will exit the study if secukinumab treatment is discontinued for more than 2 months unless the reason of treatment interval longer than 2 months are clearly addressed in medical record.

Variables and data sources

The primary outcome variable is retention rate of secukinumab therapy at 2 years after start of participation in the study by pooled indications, where retention rate is defined as percentage of patients who have not discontinued the medication.

The secondary outcome variables include:

All indications

- Retention rate of secukinumab therapy by individual indication at 1 and 2 years after start of participation in the study.
- Description of factors affecting the retention of secukinumab treatment in each indication.
- Change in EQ-5D VAS and utility scores at 6, 12, 18 and 24 months after start of participation in the study, compared to baseline before receiving the treatment with secukinumab, for each indication.
- Proportion of patients for each indication with alterations of secukinumab treatment regimen reasons for, and duration of altered treatment regimens at 6, 12, 18 and 24 months after start of participation in the study.
- Number of days of absenteeism from work/school due to health condition during each visit.

Psoriasis

- Proportions of patients achieving a PASI 75, 90, and 100 responses at 6, 12, 18 and 24 months after start of participation in the study.
- Changes between PASI response categories over time after starting participation in the study.
- Absolute PASI scores at 6, 12, 18 and 24 months after start of participation in the study.
- Changes in absolute and relative PASI scores over time, compared to baseline
- Proportion of patients achieving a PGA 0/1 response (clear/almost clear skin) at 6, 12, 18 and 24 months after start of participation in the study.
- Proportion of patients achieving a DLQI 0/1 response (0 = not at all and 1 = a little) at 6, 12, 18 and 24 months after start of participation in the study (only at sites where DLQI is part of clinical routine)
- Correlation between PASI and DLQI scores

Psoriatic arthritis

- 78 tender joint count (TJC) and 76 swollen joint count (SJC) at 1 and 2 years.
- Physician's global assessment (PGA) at 1 and 2 years.
- Total patient pain assessed by visual analog scale (VAS) at 1 and 2 years.
- Presence of any dactylitis at 1 and 2 years.
- Presence of any enthesitis at 1 and 2 years.
- Appearance of new bone erosions or worsening of pre-existing erosions in the hands and feet by X-ray assessment, according to the Treating Physician's opinion, at 1 and 2 years (if available).

- The following PASI-specific endpoints will also be assessed if applicable:
- Proportion of patients achieving a PASI 75, 90, and 100 response at 6, 12, 18 and 24 months after start of participation in the study
- Changes between PASI response categories over time after starting participation in the study.
- Absolute PASI scores at 6, 12, 18 and 24 months after start of participation in the study.
- Changes in absolute and relative PASI scores over time after inclusion into the study.
- Changes of HAQ-DI and FACIT-Fatigue scores at 6, 12, 18 and 24 months after start of participation in the study.
- Correlation between effectiveness measures, HAQ-DI, and FACIT-Fatigue scores

Ankylosing spondylitis and non-radiographic axial SpA

- Bath AS disease activity index (BASDAI) response at 1 and 2 years.
- Patient's global assessment of disease activity (numeric rating scale; NRS) at 1 and 2 years.
- C-reactive protein (CRP) or high-sensitivity CRP (hsCRP) (mg/L) at 1 and 2 years (according to clinical practice).
- Total spinal pain assessed using VAS scale at 1 and 2 years.
- Presence of any enthesitis at 1 and 2 years.
- Appearance or worsening, according to the treating physician's opinion, of any of the following lesions at anterior sites of the vertebrae assessed by X-ray at 1 and 2 years (when available)
- Appearance or worsening (according to the Treating Physician's opinion) of bone marrow edema (BME) in the spine and/or sacroiliac joints assessed by magnetic resonance imaging (MRI) at 1 and 2 years (when available).
- Changes of FACIT-Fatigue score at 6, 12, 18 and 24 months after start of participation in the study, compared to baseline.
- Correlation between ASDAS, BASDAI, and FACIT-Fatigue scores in AS.

Data sources

The present observational study will generate primary data collected prospectively for the purposes of this study. Retrospective data collection at baseline (e.g. medical and treatment history) will be also retrieved from the patient's medical record and/or hospital database.

Statistical methods

All analyses will be performed by a designated CRO using SAS platform.

For this interim 2 analysis, the data was cut off on 05 October 2023. Baseline demographics and clinical characteristics and QoL data of patients with psoriasis, psoriatic arthritis and AS were analyzed using descriptive statistics.

Results

127 patients were included in this study. The 2-year retention rate of secukinumab in overall 3 diseases was 64.57% (95% CI: 56.25–72.89%). Financial constraints were the most common reason for

drug discontinuation (31%). For patients with PsO, PASI and BSA scores decreased significantly, with none of the patients having severe disease (PASI >20) at 2 year. Among patients with PsA, tender and swollen joint counts, dactylitis, and enthesitis were substantially decreased after receiving secukinumab. For patients with AS, BASDAI, pain scores, physician global assessment, and hsCRP levels improved significantly at 2 years after receiving secukinumab. HRQoL improved across all diseases, with mean utility increasing from baseline by 0.20 (95% CI: 0.15–0.25) at 2 years.

Discussion

This study confirms the real-world effectiveness of secukinumab across PsO, PsA, and AS, demonstrating significant improvements in disease activity, clinical manifestations, HRQoL, and work/school productivity that were sustained for up to 2 years. Despite these benefits, treatment retention declined over time, with rates of 78% at 1 year and 65% at 2 years.

The 1-year retention rates observed across all three diseases were comparable to those reported in previous real-world studies, whereas the 2-year retention rates were somewhat lower. Retention was higher among biologic-naïve patients and those who initiated secukinumab at 300 mg, consistent with earlier findings that prior biologic exposure may negatively affect treatment persistence.

Notably, the most common reason for treatment discontinuation was inability to afford or obtain reimbursement for medication, while discontinuation due to lack of efficacy or adverse events was uncommon. These findings suggest that financial barriers, rather than effectiveness or safety concerns, are a key determinant of long-term secukinumab retention in Thailand.

Conclusion

Our results indicate substantial improvements in disease activity following secukinumab treatment for all patients with PsO, PsA, and AS. However, approximately 35% of patients discontinued secukinumab by 2 years. Financial barriers were the primary factor influencing treatment persistence, underscoring the critical role of reimbursement policies in supporting long-term treatment outcomes.

List of abbreviations

AE	Adverse Event
ASAS	Assessment of Spondyloarthritis International Society
ASDAS	Ankylosing Spondylitis Disease Activity Score
BSA	Body Surface Area
CRO	Contract Research Organization
CRP	C-Reactive Protein
DLQI	Dermatology Life Quality Index
EC	Ethic Committee
EQ-5D	Euro-QoL-5 Dimension Questionnaire
FACIT-Fatigue	Functional Assessment of Chronic Illness Therapy – Fatigue
HAQ-DI	Health Assessment Questionnaire-Disability Index
hsCRP	high-sensitivity CRP
IL	Interleukin
NI	Non-Interventional
NIS	Non-Interventional Study
NRS	Numeric Rating Scale
NVS	Novartis
PASI	Psoriasis Area and Severity Index
PGA	Physician Global Assessment
PRO	Patient-Reported Outcomes
PSA	Psoriatic Arthritis
QoL	Quality of Life
SJC	Swollen Joint Count
SpA	Spondyloarthritis
TJC	Tender Joint Count
VAS	Visual Analog Scale

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