



# Extension Study to Assess Effects of Non-interrupted Versus Interrupted and Long Term Treatment of Two Dose Regimes of Secukinumab in Subjects With Hidradenitis Suppurativa

13/08/2025 19:28:59

## Main Information

### Primary registry identifying number

LBCTR2020124720

### Protocol number

CAIN457M2301E1

### MOH registration number

### Study registered at the country of origin

Yes

### Study registered at the country of origin: Specify

### Type of registration

Prospective

### Type of registration: Justify

N/A

### Date of registration in national regulatory agency

### Primary sponsor

Novartis Pharma Services Inc.

### Primary sponsor: Country of origin

Novartis Pharmaceuticals

### Date of registration in primary registry

21/11/2023

### Date of registration in national regulatory agency

### Public title

Extension Study to Assess Effects of Non-interrupted Versus Interrupted and Long Term Treatment of Two Dose Regimes of Secukinumab in Subjects With Hidradenitis Suppurativa

### Acronym

### Scientific title

CAIN457M2301E1 A Multicenter, Double-blind, Randomized Withdrawal extension study of subcutaneous secukinumab to demonstrate long-term efficacy, safety and tolerability in subjects with moderate to severe hidradenitis suppurativa

### Acronym

### Brief summary of the study: English

The purpose of this extension study is to evaluate maintenance of HiSCR response at Week 104 in either continuous or interrupted therapy (using a randomized withdrawal period) of two dose regimens and to assess long-term efficacy, safety and tolerability of secukinumab in subjects with moderate to severe hidradenitis suppurativa completing either of the 2 Phase III studies. This is an expanded access trial for the core trials AIN457M2301 (NCT03713619) and AIN457M2302 (NCT03713619).

### Brief summary of the study: Arabic

دراسة تمديد وانسحاب متعددة المراكز ومزدوجة التعمية وعشوائية التوزيع حول سيكوكينوماب تحت الجلد لإثبات الفعالية والسلامة والتحمل على المدى الطويل لدى مرضى مصابين بالتهاب الغدد العرقية القيحي المتوسط إلى الشديد الحدة

### Health conditions/problem studied: Specify

Hidradenitis Suppurativa

### Interventions: Specify

Drug: secukinumab



**Key inclusion and exclusion criteria: Inclusion criteria**

- written informed consent must be obtained before any assessment is performed
- subject must have completed the study treatment period (52 weeks) in the core studies (AIN457M2301 or AIN457M2302) and have been receiving secukinumab treatment during Treatment Period 2

**Key inclusion and exclusion criteria: Gender**

Both

**Key inclusion and exclusion criteria: Specify gender****Key inclusion and exclusion criteria: Age minimum**

18

**Key inclusion and exclusion criteria: Age maximum**

99

**Key inclusion and exclusion criteria: Exclusion criteria**

- protocol deviation in the core study which will prevent the meaningful analysis of the extension study
- ongoing or planned use of prohibited HS or non-HS treatment
- participation in the extension could expose the subject to an undue safety risk
- current severe progressive or uncontrolled disease which renders the subject unsuitable for the study.

**Type of study**

Interventional

**Type of intervention**

Pharmaceutical

**Type of intervention: Specify type**

N/A

**Trial scope**

Therapy

**Trial scope: Specify scope**

N/A

**Study design: Allocation**

Randomized controlled trial

**Study design: Masking**

Blinded (masking used)

**Study design: Control**

Placebo

**Study phase**

3

**Study design: Purpose**

Treatment

**Study design: Specify purpose**

N/A

**Study design: Assignment**

Parallel

**Study design: Specify assignment**

N/A

**IMP has market authorization**

Yes, Lebanon and Worldwide

**IMP has market authorization: Specify**

US, Australia, UK, Belgium, Canada, France, Germany, Poland, Bulgaria, Greece, India, Spain, Taiwan, Turkey

**Name of IMP**

Secukinumab (Cosentyx)

**Year of authorization**

2016

**Month of authorization**

3

**Type of IMP**

Immunological

**Pharmaceutical class**

selective for human IL-17A

**Therapeutic indication**

- Patients with:
- Psoriasis (Pso)
  - Ankylosing Spondylitis (AS)
  - Psoriatic Arthritis (PsA)

**Therapeutic benefit**

time to loss of response (LOR) in HiSCR responders

**Study model**

N/A

**Study model: Specify model**

N/A

**Time perspective**

N/A

**Time perspective: Specify perspective**

N/A

**Target follow-up duration**

**Number of groups/cohorts**

**Biospecimen retention**

Samples without DNA

**Target sample size**

4

**Date of first enrollment: Type**

Actual

**Date of study closure: Type**

Actual

**Recruitment status**

Complete

**Date of completion**

30/06/2022

**IPD sharing statement plan**

No

**Additional data URL**

<https://clinicaltrials.gov/ct2/show/record/NCT04179175?term=CAIN457M2301E1&draw=2&rank=1>

**Study model: Explain model**

N/A

**Time perspective: Explain time perspective**

N/A

**Target follow-up duration: Unit**

**Biospecimen description**

Blood samples collected will be analyzed at Q2 Solutions, central lab

**Actual enrollment target size**

4

**Date of first enrollment: Date**

03/03/2021

**Date of study closure: Date**

29/12/2026

**Recruitment status: Specify**

**IPD sharing statement description**

Novartis is committed to sharing access to patient-level data and supporting clinical documents from eligible studies with qualified external researchers. Requests are reviewed and approved by an independent review panel on the basis of scientific merit. All data provided is anonymized to protect the privacy of patients who have participated in the trial in line with applicable laws and regulations.

This trial data availability is according to the criteria and process described on [www.clinicalstudydatarequest.com](http://www.clinicalstudydatarequest.com)



## Admin comments

## Trial status

Approved

## Secondary Identifying Numbers

| Full name of issuing authority | Secondary identifying number |
|--------------------------------|------------------------------|
| Clinical trials.gov            | NCT04179175                  |

## Sources of Monetary or Material Support

| Name                     |
|--------------------------|
| Novartis Pharma Services |

## Secondary Sponsors

| Name |
|------|
| NA   |

## Contact for Public/Scientific Queries

| Contact type | Contact full name | Address  | Country | Telephone    | Email                         | Affiliation                                |
|--------------|-------------------|----------|---------|--------------|-------------------------------|--|
| Public       | Hadi Hamam        | Saida    | Lebanon | 9613795246   | hadihamam@hotmail.com         | Hammoud Hospital University Medical Center |
| Scientific   | Hind Khairallah   | Sinelfil | Lebanon | 01512002#271 | Hind.khairallah@fattal.com.lb | Khalil Fattal et Fils s.a.l.               |

## Centers/Hospitals Involved in the Study

| Center/Hospital name                       | Name of principles investigator | Principles investigator speciality | Ethical approval |
|--|---------------------------------|------------------------------------|------------------|
| Hammoud Hospital University Medical Center | Hadi Hamam                      | Dermatology                        | Approved         |



## Ethics Review

| Ethics approval obtained                         | Approval date | Contact name  | Contact email               | Contact phone                |
|--|---------------|---------------|-----------------------------|------------------------------|
| Hammoud Hospital<br>University Medical<br>Center | 02/11/2020    | Ahmad Zaatari | zaatari@hammoudhospital.com | 961 (0) 7 723111 ext<br>1160 |

## Countries of Recruitment

| Name               |
|--------------------|
| Lebanon            |
| Australia          |
| Austria            |
| Belgium            |
| Bulgaria           |
| Canada             |
| Czech Republic     |
| France             |
| Germany            |
| Greece             |
| Hungary            |
| India              |
| Italy              |
| Japan              |
| Republic of Korea  |
| Lithuania          |
| Malaysia           |
| Poland             |
| Portugal           |
| Russian Federation |
| Singapore          |



|                          |
|--------------------------|
| Slovakia                 |
| South Africa             |
| Spain                    |
| Switzerland              |
| Taiwan                   |
| Turkey                   |
| United Kingdom           |
| United States of America |
| Viet Nam                 |

## Health Conditions or Problems Studied

| Condition                | Code                      | Keyword                  |
|--------------------------|---------------------------|--------------------------|
| Hidradenitis Suppurativa | Skin, unspecified (D23.9) | Hidradenitis Suppurativa |

## Interventions

| Intervention   | Description  | Keyword  |
|--|--|--|
| Informed Consent form discussion; Inclusion/exclusion assessment; physical examination; blood samples collection; questionnaires review and assessment; IMP dispensation | Informed Consent form discussion; Inclusion/exclusion assessment; physical examination; blood samples collection; questionnaires review and assessment; IMP dispensation | Informed Consent form discussion; Inclusion/exclusion assessment; physical examination; blood samples collection; questionnaires review and assessment; IMP dispensation |

## Primary Outcomes

| Name   | Time Points  | Measure      |
|--|--------------|--------------|
| time to loss of response (LOR) in HiSCR responders | Weeks 52-104 | Weeks 52-104 |

## Key Secondary Outcomes

| Name  | Time Points | Measure  |
|---|-------------|----------|
| Cumulative rate of subjects who experience a flare in core HiScr responders | Week 104    | Week 104 |
| subjects achieving NRS30  | Week 104    | Week 104 |



## Trial Results

Summary results

Study results globally

Date of posting of results summaries

Date of first journal publication of results

Results URL link

Baseline characteristics

Participant flow

Adverse events

Outcome measures

URL to protocol files