



# 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

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## 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**

09/05/2021

**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 sever 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: Explain model**

N/A

**Study model: Specify model**

N/A

**Time perspective**

N/A

**Time perspective: Explain time perspective**

N/A

**Time perspective: Specify perspective**

N/A

**Target follow-up duration****Target follow-up duration: Unit****Number of groups/cohorts****Biospecimen retention**

Samples without DNA

**Biospecimen description**

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

**Target sample size**

3

**Actual enrollment target size****Date of first enrollment: Type**

Anticipated

**Date of first enrollment: Date**

05/02/2021

**Date of study closure: Type**

Anticipated

**Date of study closure: Date**

29/12/2026

**Recruitment status**

Pending

**Recruitment status: Specify****Date of completion**

30/06/2022

**IPD sharing statement plan**

No

**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)

**Additional data URL**

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

**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 University Medical Center	02/11/2020	Ahmad Zaatari	zaatari@hammoudhospital.com	961 (0) 7 723111 ext 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**