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

14/08/2025 06:01:22

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
02/07/2025

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 وعشوائيّة التوزيع حول سيكوكينوماب تحت الجلد لإثبات الفعالية والسلامة والتحمّل على المدى الطويل لدى مرضى مصابين بالتهاب الغدد العرقيّة القيحيّ المتوسّط إلى الشديد الحدّة

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 reponders

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

4

Actual enrollment target size

4

Date of first enrollment: Type

Actual

Date of first enrollment: Date

03/03/2021

Date of study closure: Type

Actual

Date of study closure: Date

29/12/2026

Recruitment status

Complete

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

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 Khairallh	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 reponders	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