Open-label, Long-term Safety Study of Secukinumab in Polymyalgia Rheumatica (PMR)

11/09/2025 17:09:55

Main Information

Primary registry identifying number
LBCTR2024065610

Protocol number
CAIN457C22301E1

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 AG

Primary sponsor: Country of origin
Novartis Pharma AG

Date of registration in primary registry
11/02/2025

Date of registration in national regulatory agency

Public title
Open-label, Long-term Safety Study of Secukinumab in Polymyalgia Rheumatica (PMR)

Acronym

Scientific title
A Multi-center, Open-label Extension Study of Subcutaneous Secukinumab to Evaluate the Long-term Safety and Tolerability in Polymyalgia Rheumatica (PMR)

Acronym

Brief summary of the study: English
The purpose of this extension study is to assess the safety and tolerability of secukinumab when administered long-term in patients with polymyalgia rheumatica.

Brief summary of the study: Arabic
دراسة تمديد متعددة المراكز ومفتوحة التسمية حول دواء سيكوكينوماب المعطى تحت الجلد لتقييم سلامته وتحمّ له على المدى الطويل في علاج ألم العضلات الروماتيزمي

Health conditions/problem studied: Specify
Polymyalgia Rheumatica

Interventions: Specify
Biological: Secukinumab
2 x 150mg/1mL PFS secukinumab

Key inclusion and exclusion criteria: Inclusion criteria
Inclusion Criteria:
-Participants who have completed 52-week Treatment Period as per protocol in a Novartis study of secukinumab in PMR patients (the "core study" - Study CAIN457C22301), AND
-who have experienced a relapse during the treatment-free follow-up period of the core study, AND
-who have not been on rescue treatment.
-The participant would potentially derive benefit from secukinumab, and the benefit outweighs the risk, based on the investigator's judgement.

Key inclusion and exclusion criteria: Gender

Both

Key inclusion and exclusion criteria: Specify gender

Key inclusion and exclusion criteria: Age minimum

50

Key inclusion and exclusion criteria: Age maximum

99

Key inclusion and exclusion criteria: Exclusion criteria

Exclusion Criteria:
-Use of prohibited medications, as specified in the protocol
-History of ongoing, chronic or recurrent infectious disease (i.e., human immunodeficiency virus (HIV), hepatitis B (HBV), hepatitis C (HCV), active tuberculosis infection (TB))
-History of lymphoproliferative disease or any known malignancy or history of malignancy of any organ system within the past 5 years (except for basal cell carcinoma or actinic keratosis that have been treated with no evidence of recurrence in the past 3 months carcinoma in situ of the cervix or non-invasive malignant colon polyps that have been removed).
-Live vaccinations (e.g., monkey pox vaccine, oral polio vaccine, varicella/zoster vaccines) within 6 weeks prior to Baseline
-Subjects whose participation in the extension study could expose them to an undue safety risk

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

N/A

Study design: Masking

Open (masking not used)

Study design: Control

N/A

Study phase

3

Study design: Purpose

Treatment

Study design: Specify purpose

N/A

Study design: Assignment

Single

Study design: Specify assignment

N/A

IMP has market authorization

Yes, Lebanon and Worldwide

IMP has market authorization: Specify

Switzerland, UK, France, Italy, Portugal, Belgium, Spain, Canada, United States, Australia,,Jordan, KSA, Oman, Kuwait, UAE, Qatar, Bahrain

Name of IMP

Secukinumab

Year of authorization

2016

Month of authorization

3

Type of IMP

Immunological

Pharmaceutical class

Interleukin 17A inhibitor (IL-17i)

Therapeutic indication

Polymyalgia Rheumatica (PMR)

Therapeutic benefit

Treatment

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 with DNA**

Biospecimen description
shipped to Q2 central lab

Target sample size
8

Actual enrollment target size

Date of first enrollment: Type
Anticipated

Date of first enrollment: Date
01/03/2025

Date of study closure: Type
Anticipated

Date of study closure: Date
25/01/2028

Recruitment status
Pending

Recruitment status: Specify

Date of completion

IPD sharing statement plan
Yes

IPD sharing statement description
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 by an independent review panel on the basis of scientific merit. All data provided is anonymized to respect 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://www.clinicaltrials.gov/study/NCT06331312?term=CAIN457C22301E1&rank=1

Admin comments

Trial status

Approved

Secondary Identifying Numbers

Full name of issuing authority	Secondary identifying number
Clinicaltrials.gov	NCT06331312

Sources of Monetary or Material Support

Name
Novartis Pharma AG

Secondary Sponsors

Name
NA

Contact for Public/Scientific Queries

Contact type	Contact full name	Address	Country	Telephone	Email	Affiliation
Public	Nelly Ziade	Hotel Dieu de France Hospital, Asrafieh, Lebanon	Lebanon	009617097 3214	nelly.zoghbi@usj.edu.lb	Hotel Dieu de France Hospiital
Scientific	Hind Khairallah	Sin El Fil	Lebanon	009611512 002 Ext. 271 E	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
Hotel Dieu de France Hospital	Nelly Ziade	Rheumatology	Approved

Ethics Review

Ethics approval obtained	Approval date	Contact name	Contact email	Contact phone
Hotel Dieu de France	26/03/2024	Sami Richa	cue@usj.edu.lb	00961421229

Countries of Recruitment

Name
Australia
Japan
Switzerland
United States of America
Czech Republic
Denmark
Germany
Italy
Netherlands
Spain

Health Conditions or Problems Studied

Condition	Code	Keyword
Polymyalgia rheumatica	Polymyalgia rheumatica (M35.3)	Polymyalgia rheumatica

Interventions

Intervention	Description	Keyword
Consenting, IMP administration, Laboratory testing, imaging	Consenting, IMP administration, Laboratory testing, imaging	Consenting, IMP administration, Laboratory testing, imaging

Primary Outcomes

Name	Time Points	Measure
Incidences of treatment emergent adverse events (AEs) and serious adverse events (SAEs)	Time Frame: After the first dose of study treatment and within 84 days after the last dose	The number and percentage of participants with treatment emergent AEs/SAEs will be summarized. No hypothesis testing will be performed.

Key Secondary Outcomes

Name	Time Points	Measure
not provided	not provided	not provided

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