



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

22/11/2024 05:40:36

## 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**

13/08/2024

**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 وتحمل 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: Specify type**

N/A

**Type of intervention**

Pharmaceutical

**Trial scope: Specify scope**

N/A

**Trial scope**

Therapy

**Study design: Masking**

Open (masking not used)

**Study design: Allocation**

N/A

**Study phase**

3

**Study design: Control**

N/A

**Study design: Specify purpose**

N/A

**Study design: Purpose**

Treatment

**Study design: Specify assignment**

N/A

**Study design: Assignment**

Single

**IMP has market authorization: Specify**

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

**IMP has market authorization**

Yes, Lebanon and Worldwide

**Year of authorization**

2016

**Month of authorization**

3

**Name of IMP**

Secukinumab

**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: 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 with DNA\*\*

**Target sample size**

8

**Date of first enrollment: Type**

Anticipated

**Date of study closure: Type**

Anticipated

**Recruitment status**

Pending

**Date of completion****IPD sharing statement plan**

Yes

**Additional data URL**

<https://www.clinicaltrials.gov/study/NCT06331312?term=CAIN457C22301E1&rank=1>

**Study model: Explain model**

N/A

**Time perspective: Explain time perspective**

N/A

**Target follow-up duration: Unit****Biospecimen description**

shipped to Q2 central lab

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

17/12/2024

**Date of study closure: Date**

25/01/2028

**Recruitment status: Specify****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](http://www.clinicalstudydatarequest.com)



## 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	0096170973214	nelly.zoghbi@usj.edu.lb	Hotel Dieu de France Hospital
Scientific	Hind Khairallah	Sin El Fil	Lebanon	009611512002 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**