



# Phase III Study of Efficacy and Safety of Secukinumab Versus Placebo, in Combination With Glucocorticoid Taper Regimen, in Patients With Polymyalgia Rheumatica (PMR)

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## Main Information

### Primary registry identifying number

LBCTR2023035313

### Protocol number

CAIN457C22301

### 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

13/09/2023

### Date of registration in national regulatory agency

### Public title

Phase III Study of Efficacy and Safety of Secukinumab Versus Placebo, in Combination With Glucocorticoid Taper Regimen, in Patients With Polymyalgia Rheumatica (PMR)

### Acronym

### Scientific title

A Randomized, Parallel-group, Double-blind, Placebo-controlled, Multicenter Phase III Trial to Evaluate Efficacy and Safety of Secukinumab Administered Subcutaneously Versus Placebo, in Combination With a Glucocorticoid Taper Regimen, in Patients With Polymyalgia Rheumatica (PMR)

### Acronym

### Brief summary of the study: English

The purpose of this study is to demonstrate the efficacy and safety of secukinumab 300 milligram (mg) and 150 mg administered subcutaneously (s.c.) for 52 weeks in combination with prednisone tapered over 24 weeks in adult participants with PMR who have recently relapsed

### Brief summary of the study: Arabic

تجربة عشوائية التوزيع ومتوازنة المجموعات ومزدوجة التعمية ومركزة على المقارنة بدواء وهمي ومتعددة المراكز في المرحلة الثالثة، لتقييم فعالية وسلامة دواء سيكوكينوماب المعطى تحت الجلد مقابل الدواء الوهمي، بالاشتراك مع نظام تقليل تدريجي للهرمونات القشرية السكرية، لدى مرضى مصابين بألم العضلات الروماتيزمي

### Health conditions/problem studied: Specify

Polymyalgia Rheumatica

### Interventions: Specify

Drug: Secukinumab 300 mg  
Taken subcutaneously every 4 weeks until Week 48 in combination with a 24-week prednisone taper regimen





Other Name: AIN457

Drug: Secukinumab 150 mg

Taken subcutaneously every 4 weeks until Week 48 in combination with a 24-week prednisone taper regimen

Other Name: AIN457

Other: Placebo to secukinumab

Taken subcutaneously every 4 weeks until Week 48 in combination with a 24-week prednisone taper regimen

## Key inclusion and exclusion criteria: Inclusion criteria

### Inclusion Criteria:

- 1- Signed informed consent must be obtained prior to participation in the study
- 2- Male or non-pregnant, non-lactating female participants at least 50 years of age.
- 3- Diagnosis of PMR according to the provisional American College of Rheumatology (ACR)/European League Against Rheumatism (EULAR) classification criteria: Participants  $\geq 50$  years of age with a history of bilateral shoulder pain accompanied by elevated C-reactive protein (CRP) concentration ( $\geq 10$  mg/L) and/or elevated erythrocyte sedimentation rate (ESR) ( $\geq 30$  mm/hr) who scored at least 4 points from the following optional classification criteria:

Morning stiffness  $> 45$  minutes (min) (2 points)

Hip pain or restricted range of motion (1 point)

Absence of rheumatoid factor and/or anti-citrullinated protein antibodies (2 points)

Absence of other joint involvement (1 point)

4- Participants must have a history of being treated for at least 8 consecutive weeks with prednisone ( $\geq 10$  mg/day or equivalent) at any time prior to screening

5- Participants must have had at least one episode of PMR relapse while attempting to taper prednisone at a dose that is  $\geq 5$  mg/day (or equivalent) within the past 12 weeks prior to BSL. Diagnosis of a PMR relapse is defined as participant meeting both of the following:

Recurrence of bilateral shoulder girdle and/or bilateral hip girdle pain associated with inflammatory stiffness with or without additional symptoms indicative of PMR relapse (such as constitutional symptoms) within 12 weeks prior to BSL that are in the opinion of the Investigator not due to other diseases that may mimic PMR such as osteoarthritis in shoulders or hips, polyarticular calcium pyrophosphate deposition disease, rotator cuff disease, adhesive capsulitis (frozen shoulder) or fibromyalgia.

Elevated ESR ( $\geq 30$  mm/hr) and/or elevated CRP ( $>$  upper limit of normal (ULN)) attributable to PMR at the time of relapse and/or at screening

6- Participants must have been treated as per local treatment recommendations following the latest PMR relapse and must be on prednisone of at least 7.5 mg/day (or equivalent) and not exceeding 25 mg/day at screening and during the screening period

Other protocol-defined inclusion/exclusion criteria may apply

## 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:

- 1- Evidence of GCA as indicated by typical (cranial) symptoms (e.g., persistent or recurrent localized headache, temporal artery or scalp tenderness, jaw claudication, blurry or loss of vision, symptoms of stroke), extremity claudication, imaging and/or temporal artery biopsy result
  - 2- Concurrent rheumatoid arthritis or other inflammatory arthritis or other connective tissue diseases, such as but not limited to systemic lupus erythematosus, systemic sclerosis, vasculitis, myositis, mixed connective tissue disease, and ankylosing spondylitis
  - 3- Concurrent diagnosis or history of neuropathic muscular diseases
- Inadequately treated hypothyroidism (e.g., persistence of symptoms, lack of normalization of serum TSH despite regular hormonal replacement treatment)
- 4- Previous exposure to secukinumab or other biologic drug directly targeting IL-17 or IL-17 receptor
  - 5- Participants treated with tocilizumab or other IL-6/IL6-receptor inhibitors within 12 weeks or within 5 half-lives (whichever is longer) prior to BSL; participant who did not respond to or experienced a relapse during treatment are excluded from enrollment into the study

Other protocol-defined inclusion/exclusion criteria may apply

## 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

## Study design: Masking

Randomized controlled trial

**Study design: Control**

Placebo

**Study design: Purpose**

Treatment

**Study design: Assignment**

Parallel

**IMP has market authorization**

Yes, Lebanon and Worldwide

**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\*\*

Blinded (masking used)

**Study phase**

3

**Study design: Specify purpose**

N/A

**Study design: Specify assignment**

N/A

**IMP has market authorization: Specify**

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

**Year of authorization**

2016

**Month of authorization**

3

**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

**Target sample size**

10

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

Anticipated

**Date of first enrollment: Date**

30/06/2023

**Date of study closure: Type**

Anticipated

**Date of study closure: Date**

22/12/2025

**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](http://www.clinicalstudydatarequest.com)

**Additional data URL**

<https://clinicaltrials.gov/ct2/show/record/NCT05767034?term=CAIN457C22301&draw=2&rank=1>

**Admin comments****Trial status**

Approved

## Secondary Identifying Numbers

Full name of issuing authority	Secondary identifying number
Clinicaltrials.gov	NCT05767034

## 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
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Public	Kamel Mroue	Hammoud Hospital University Medical Center, Saïda, Lebanon	Lebanon	009613844769	khmroue@gmail.com	Hammoud Hospital University Medical Center

## 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
Hammoud Hospital University Medical Center	Kamel Mroue	Rheumatology	Approved

## Ethics Review

Ethics approval obtained	Approval date	Contact name	Contact email	Contact phone
Hotel Dieu de France	07/02/2023	Sami Richa	cue@usj.edu.lb	00961421229
Hammoud Hospital University Medical Center	12/12/2022	Ibrahim Omeis	iomeis@hammoudhospital.org	+961 (0) 7 723111 ext 1222/ 1223



## Countries of Recruitment

Name
United States of America
Switzerland
Argentina
Australia
Canada
Japan

## 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
Proportion of patients achieving complete sustained remission	Time Frame: 52 Weeks	Sustained remission at Week 52 is defined as a participant meeting all of the following: • achieved remission at Week 12 AND all of the following, sustained from Week 12 to Week 52: no recurrence of signs or symptoms, attributable to PMR, that requires escape treatment or rescue treatment no new diagnosis of Giant cell arteritis (GCA), that requires escape treatment or rescue treatment Remission at Week 12 is defined as a participant meeting all of the following at Week 12: no use of escape treatment or rescue treatment prior to Week 12 no signs or symptoms attributable to PMR, that requires escape treatment or use of rescue treatment, at Week 12 no new diagnosis of GCA, that requires escape treatment or rescue treatment, at Week 12



## Key Secondary Outcomes

Name	Time Points	Measure
Proportion of patients achieving complete sustained remission	Time Frame: 52 Weeks	Complete sustained remission at Week 52 is defined as participant meeting all of the following: achieved sustained remission no clinically relevant elevation of Erythrocyte sedimentation Rate (ESR) and/or C-reactive protein (CRP) at $\geq 2$ consecutive scheduled visits from Week 12 to Week 52
Adjusted annual cumulative glucocorticoid (GC) dose adjusted by duration of study follow-up	Time Frame: 52 Weeks	Adjusted annual cumulative GC dose is cumulative GC dose through Week 52 adjusted by duration of study follow-up
Time to first use of escape treatment or rescue treatment as measured in days	Time Frame: 52 Weeks	First use of escape treatment or rescue treatment is defined as the first time when the escape treatment or rescue treatment is used
Change in FACIT-Fatigue Score	Time Frame: 52 Weeks	The Functional Assessment of Chronic Illness Therapy - Fatigue (FACIT-Fatigue) is a 13-item questionnaire that assesses self-reported fatigue and its impact upon daily activities and function. The purpose of collecting available FACIT-Fatigue data is to assess the impact of fatigue on participants with PMR
Change in HAQ-DI score	Time Frame: 52 Weeks	The Health Assessment Questionnaire - Disability Index (HAQ-DI) is used to assess the long-term influence of chronic disease on a participant's level of functional ability and activity restriction. The purpose of the HAQ-DI is to assess the functional ability of subjects with PMR



## 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