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
21/11/2023

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 عشوائيّة التوزيع ومتوازية المجموعات ومزدوجة التعمية ومرتكزة على المقارنة بدواء وهمي ومتعدّ دة المراكز في المرحلة الثالثة، لتقييم فعاليّة وسلامة دواء سيكوكينوماب المعطى تحت الجلد مقابل الدواء الوهمي، بالاشتراك مع نظام تقليل تدريجيّ للهرمونات القشريّة 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 ≥ 50 years of age with a history of bilateral shoulder pain accompanied by elevated C-reactive protein (CRP) concentration (≥ 10 mg/L) and/or elevated erythrocyte sedimentation rate (ESR) (≥ 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 (≥ 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 ≥ 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 (≥ 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

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

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

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

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	009617097 3214	nelly.zoghbi@usj.edu.lb	Hotel Dieu de France Hospiital
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Public	Lama Azar	Saint George Hospital University Medical Center, Beirut,Lebanon	Lebanon	009617918 8303	leazar@stgeorgehospital.org	Saint George 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
Saint George Hospital University Medical Center	Lama Azar	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
Saint George Hospital University Medical Center	11/08/2023	Michel Daher	mndaher@stgeorgehospital.org	009611441733

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 ≥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