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

Last Update: Mar 30, 2025
A Multi-center, Open-label Extension Study of Subcutaneous Secukinumab to Evaluate the Long-term Safety and Tolerability in Polymyalgia Rheumatica (PMR)
ClinicalTrials.gov Identifier:
NCT06331312
Novartis Reference Number:CAIN457C22301E1
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All compounds are either investigational or being studied for (a) new use(s). Efficacy and safety have not been established. There is no guarantee that they will become commercially available for the use(s) under investigation.

Study Description

The purpose of this extension study is to assess the safety and tolerability of secukinumab when administered long-term in patients with polymyalgia rheumatica. The study will consist of an up to 4-week screening period, an up to 2-year Treatment Period which includes two Treatment Periods, and a 16-week treatment-free follow-up period (20 weeks post last dose of secukinumab).

Treatment period:

There will be two Treatment Periods (TPs): TP1 will be from the first dose administration of secukinumab (Baseline) to Week 24, where visits will occur every 4 weeks, and TP2 will be from post Week 24 visit (post-dose) to up to 2 years. Participants will return to the study site every 4 weeks from Baseline until Week 24 (Weeks 16 and 20 visits are optional on-site visits and needed when participants are unwilling/uncomfortable to self-administer study treatment at home/offsite), then every 12 weeks afterwards in TP2 for resupply of study medication but may return earlier if needed (i.e., those participants who are unwilling/uncomfortable to self-administer study treatment can continue to visit site every 4 weeks for drug administration if they wish to do so).

Follow-up period: An EoS visit (20 weeks after last administration of secukinumab) will be done for all participants, regardless of whether they complete the entire study as planned, or they discontinue prematurely.

Condition
Polymyalgia Rheumatica
Phase
Phase3
Overall Status
Recruiting
Number of Participants
300
Start Date
Jun 28, 2024

Completion Date
Feb 10, 2028
Gender
All
Age(s)
50 Years - 100 Years (Adult, Older Adult)

Interventions

Biological

Secukinumab

2 x 150mg/1mL PFS secukinumab

Eligibility 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.

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

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