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

NCT06331312

Status	RECRUITING
Phase	Phase 3
Sponsor	Novartis Pharmaceuticals
Enrollment	288 participants

Key Eligibility Criteria

Inclusion (4)

- 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 (5)

- 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

Locations (115 total)

Arizona Arthritis and Rheumatology Associates PLLC, Avondale, Arizona, United States
Sun Valley Arthritis Center Ltd, Peoria, Arizona, United States
Orrin Troum MD and Medical Associates, Santa Monica, California, United States
... and 112 more locations