

Secukinumab Open Label Roll-over Extension Protocol

NCT04638647

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| Status | RECRUITING |
| Phase | Phase 4 |
| Sponsor | Novartis Pharmaceuticals |
| Enrollment | 1,000 participants |

Key Eligibility Criteria

Inclusion (5)

- Signed informed consent must be obtained for adult participants before any assessment is performed. Written informed assent and parental permission (age as per local law) must be obtained for pediatric participants before any assessment is performed. If participants reach age of consent (age as per local law) during the study, they will need to also sign the corresponding study informed consent(s).
- Ability to communicate effectively with the investigator, to understand and willing to comply with the requirements of the study.
- Participant has completed treatment per protocol in a Novartis study of secukinumab (unless otherwise specified in a parent study protocol). Participants, who derive benefit from the treatment with secukinumab but have not completed the treatment in certain parent studies, due to parent study termination by Novartis, may be eligible if the termination was due to reasons other than safety or lack of efficacy (technical / administrative reasons).
- Participant is deriving benefit from secukinumab, investigator believes he/she would continue to derive benefit from secukinumab and the benefit outweighs the risk, based on the investigator's judgement.
- Participant is unable to obtain access to the marketed secukinumab formulation per local prescription and/or reimbursement guidelines.

Exclusion (2)

- Participant has prematurely discontinued study treatment in the parent protocol.
- Women of childbearing potential, defined as all women physiologically capable of becoming pregnant, unless they are using methods of contraception during the entire study or longer if required by locally approved prescribing information (e.g., in European Union (EU) 20 weeks).

Locations (167 total)

Providence Medical Foundation, Fullerton, California, United States
Purushotham Akther and Roshan Kotha MD Inc, La Mesa, California, United States
Precn Comprehensive Clnl Rsch Solns, San Leandro, California, United States
... and 164 more locations

<https://clinicaltrials.gov/study/NCT04638647>

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