Secukinumab Open Label Roll-over Extension Protocol

Last Update: Jun 05, 2025
An Open-label, Multi-center Protocol for Patients Who Have Completed a Previous Novartis Sponsored Secukinumab Study and Are Judged by the Investigator to Benefit From Continued Secukinumab Treatment
ClinicalTrials.gov Identifier:
NCT04638647
Novartis Reference Number:CAIN457A02001B
See if you Pre-qualify
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 study is to assess long term safety in participants who have completed a Novartis trial with secukinumab, have been judged by the investigator to benefit from continued treatment with secukinumab, and are unable to obtain the marketed secukinumab formulation.

Condition
Autoimmunity, Inflammation
Phase
Phase4
Overall Status
Recruiting
Number of Participants
715
Start Date
Dec 22, 2020
Completion Date
Apr 04, 2030
Gender
All
Age(s)
6 Years - 100 Years (Child, Adult, Older Adult)

Interventions

Biological

Secukinumab s.c. injection

Secukinumab pre-filled syringes (PFS) for s.c. injection

Eligibility Criteria

Inclusion Criteria:

1. 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).
2. Ability to communicate effectively with the investigator, to understand and willing to comply with the requirements of the study.
3. 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).
4. 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.
5. Participant is unable to obtain access to the marketed secukinumab formulation per local prescription and/or reimbursement guidelines.

Exclusion Criteria:

1. Participant has prematurely discontinued study treatment in the parent protocol.
2. 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).

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