Secukinumab Drug Survival, Effectiveness and Tolerability in Pediatric Patients With Psoriasis

Last Update: Jan 14, 2025
Prospective Observational Study With Retrospective Part to Evaluate Secukinumab Drug Survival, Effectiveness and Tolerability in Pediatric Patients With Moderate-to-severe Plaque Psoriasis
ClinicalTrials.gov Identifier:
NCT06142357
Novartis Reference Number:CAIN457LRU01
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

Multicenter, non-interventional, cohort study in pediatric patients with moderate to severe plaque-type psoriasis. Retrospective data collection is planned at patients' inclusion. This observational study will be performed at healthcare facilities treating pediatric psoriasis patients. The study population will consist of a representative group of pediatric patients with moderate-to-severe plaque psoriasis for whom routine treatment with secukinumab according to the approved national label is initiated during 4 to 16 weeks Retrospective data collection is planned at patients' inclusion. Prospective data collection will continue during follow-up routine visits until secukinumab discontinuation or maximum duration of follow-up for 104 weeks after index date.

Condition
Moderate-to-severe Plaque Psoriasis
Overall Status
Recruiting
Number of Participants
200
Start Date
Dec 29, 2023
Completion Date
Jul 31, 2027
Gender
All
Age(s)
6 Years - 18 Years (Child, Adult)

Interventions

Other

Secukinumab

There is no treatment allocation. Patients administered secukinumab by prescription will be enrolled

Eligibility Criteria

Inclusion Criteria:

1. Written informed consent and legal representative's permission for study participation obtained prior to beginning of participation in the study.
2. Age ≥6 to \<18 years old.
3. Established diagnosis of active moderate-to-severe plaque psoriasis defined as a PASI score ≥ 10, body surface area (BSA) involvement of ≥10% and PGA score ≥ 3 only or with concomitant psoriatic arthritis.
4. Failure or intolerance of prior psoriasis treatment.
5. Patient was prescribed with secukinumab within 4-16 weeks before inclusion.
6. Decision for secukinumab prescription was made by the attending physician according to the approved national label during routine clinical practice, regardless of this non-interventional study conduct.

Exclusion Criteria:

1. Known or suspected severe hypersensitivity for secukinumab, formulation excipients, or injection device components (i.e., latex).
2. History of chronic recurrent infection.
3. Clinically significant infection exacerbation, including active tuberculosis.
4. Age \<6 years or ≥18 years.
5. Pregnancy and breastfeeding.
6. Patients participating in parallel in an interventional clinical trial.
7. Patients participating in parallel in other Novartis-sponsored non-interventional study generating primary data for secukinumab.
8. Patients within the safety follow-up phase of interventional study.
9. Active inflammatory bowel disease at inclusion.
10. Patients who received any vaccine within 4 weeks prior to secukinumab initiation.
11. Any medical or psychological condition in the investigator's opinion which may prevent the study participation.

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Source URL: *https://prod1.novartis.com/clinicaltrials/study/nct06142357*

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2. #trial-eligibility
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