Long Term Observational Study to Collect in a Real-world populatIon Data on the Treatment Pattern of secukinumAb in Adult Patients With Moderate to Severe Hidradenitis Suppurativa.

Last Update: Jan 14, 2025
Long Term observAtional, Prospective, Multicenter Study to Collect iN a Real-world populatIon Data on the treatMent Pattern of secukinumAb in Adult Patients With Moderate to Severe Hidradenitis Suppurativa (HS) (ANIMA)
ClinicalTrials.gov Identifier:
NCT05921994
Novartis Reference Number:CAIN457MDE01
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 observational, prospective, non-interventional, multicenter, open-label, single arm study in Hidradenitis suppurativa (HS) is to assess the treatment pattern of secukinumab in a flexible dosing regimen and decision influencing factors for flexible dosing in a real-world population over 2 years. The study will collect data from patients during routine secukinumab treatment and will be representative of the real-world patient population eligible for secukinumab treatment in Germany.

In order to attain widespread representation of health care practices related to the use of secukinumab in the approved indication of moderate to severe HS, a broad spectrum of dermatology practices and clinics who are treating patients with HS across Germany will be included.

Condition
Hidradenitis Suppurativa
Overall Status
Recruiting
Number of Participants
600
Start Date
Aug 10, 2023
Completion Date
Dec 22, 2026
Gender
All
Age(s)

18 Years - 99 Years (Adult, Older Adult)

Interventions

Other

secukinumab

Prospective observational study. There is no treatment allocation. Patients administered secukinumab by prescription and administered according to the SmPC.

Eligibility Criteria

Inclusion Criteria:

Patients eligible for inclusion in this study have to fulfill all of the following criteria at enrollment:

1. Patients who provide written informed consent to participate in the study
2. Male and female patients with ≥18 years of age
3. Diagnosis of clinically unequivocal moderate to severe HS
4. Patients for whom a therapy with secukinumab is medically indicated
5. Documented decision for treatment with marketed secukinumab regardless of this noninterventional study
6. Treatment with secukinumab according to the latest version of SmPC
7. Initial treatment with marketed secukinumab planned for up to 1 week before the baseline visit

Exclusion Criteria:

Patients fulfilling any of the following criteria at enrollment are not eligible for inclusion in this study. No additional exclusions may be applied by the investigator, in order to ensure that the study population will be representative of all eligible patients:

1. Patients who have any contraindications, such as a history of or active inflammatory bowel disease (Crohn ´s disease, ulcerative colitis), and are not eligible for treatment with secukinumab according to the SmPC
2. Any medical or psychological condition in the treating physician's opinion which may prevent the patient from the study participation
3. Simultaneous participation in any investigational trial or simultaneous participation in another Novartis-sponsored non-interventional study with secukinumab
4. Previous exposure to IL-17 inhibitors
5. For biologic-naïve patients, previous exposure to another biologic drug, such as anti-TNF-α inhibitors

Germany

Novartis Investigative Site

Recruiting

Kempen,47906,Germany

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Recruiting

Peitz,03185,Germany

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Chemnitz,09113,Germany

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Recruiting

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Recruiting

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Kiel,24103,Germany

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Recruiting

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Recruiting

Aachen,52064,Germany

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Recruiting

Schweinfurt,97421,Germany

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Duren,52349,Germany

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Berlin,13086,Germany

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Hamburg,20457,Germany

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Moenchengladbach,41063,Germany

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Dresden,01307,Germany

Novartis Investigative Site

Recruiting

Kronach,96317,Germany

Novartis Investigative Site

Recruiting

Gladbeck,45964,Germany

Novartis Investigative Site

Recruiting

Marburg,35043,Germany

Novartis Investigative Site

Recruiting

Bergen,18528,Germany

Worldwide Contacts

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Novartis Pharmaceuticals

Phone: +41613241111
Email: novartis.email@novartis.com

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