A Study of Secukinumab to Evaluate Maintenance of Response in Participants With Non-radiographic Axial Spondyloarthritis Who Achieved Remission

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A Multicenter Study of Secukinumab, With a Randomized Double-blind, Placebo-controlled Withdrawal-retreatment Period, to Evaluate Maintenance of Response in Participants With Non-radiographic Axial Spondyloarthritis Who Achieved Remission

ClinicalTrials.gov Identifier:

NCT05622708

Novartis Reference Number:CAIN457I2401

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

This study will establish whether prolonged chronic dosing with secukinumab is needed in participants with Non-radiographic axial spondyloarthritis, (nr-axSpA) who have achieved remission. Remission is defined as Ankylosing Spondylitis Disease Activity Score - C-reactive protein (ASDAS-CRP) Inactive Disease (ID) response (ASDAS-CRP \< 1.3). Maintenance of remission on continued secukinumab treatment will be evaluated compared to placebo using a randomized withdrawal design. The primary outcome measure for this study is the proportion of participants remaining flare-free at Week 120. This study will establish whether prolonged chronic dosing with secukinumab is needed in participants with nr-axSpA who have achieved remission. Remission is defined as Ankylosing Spondylitis Disease Activity Score - C-reactive protein (ASDAS-CRP) Inactive Disease (ID) response Inactive Disease (ID) response (ASDAS-CRP \< 1.3). The maintenance of remission on continued secukinumab treatment will be evaluated compared to placebo using a randomized withdrawal design. The primary outcome measure for this study is the proportion of participants remaining flare-free at Week 120.

Study treatment will be as follows:

* Open-label Secukinumab PFS (prefilled syringe) will be labeled as AIN457 150mg/1mL
* Double-blind Secukinumab and Placebo PFS will be labeled as AIN457 150mg/1mL/Placebo.

Study duration will be up to 128 weeks from Baseline.

The treatment duration will be up to 120 weeks with last treatment administration at Week 116.

In the Treatment Period 1 participant will attend a site visit approximately 1 month after Baseline and approximately every 12 weeks thereafter. In the Treatment Period 2 participant will attend site visits approximately every 4 weeks.

Condition

Non-radiographic Axial Spondyloarthritis
Phase
Phase4
Overall Status
Recruiting
Number of Participants
340
Start Date
Mar 28, 2023
Completion Date
Jun 21, 2030
Gender
All
Age(s)
18 Years - 100 Years (Adult, Older Adult)

Interventions

Drug

Placebo

Treatment Period 2: Double-blind placebo PFS s.c. every 4 weeks from Week 56 to Week 116.
Drug

Secukinumab

Treatment Period 2: Double-blind secukinumab 150 mg PFS s.c. every 4 weeks from Week 56 to Week 116.
Escape re-treatment (during Treatment Period 2): Open-label secukinumab 150 mg PFS s.c.

Eligibility Criteria

Inclusion Criteria:

* Male or non-pregnant, non-lactating female participants at least 18 years of age
* Clinical diagnosis of axSpA AND according to ASAS axSpA criteria:

1. Inflammatory back pain for at least 6 months
2. Onset before 45 years of age
3. Sacroiliitis on MRI (magnetic resonance imaging) (as assessed by central reader) with ≥ 1 SpA feature OR HLA-B-27 positive with ≥2 SpA features

* Objective signs of inflammation at screening, evident by either MRI with Sacroiliac Joint inflammation (as assessed by central reader) AND / OR hsCRP \> ULN (as defined by the central lab)
* Active axSpA as assessed by total BASDAI ≥ 4 cm (0-10 cm) at baseline.
* Spinal pain as measured by BASDAI question #2 ≥ 4 cm (0-10 cm) at baseline.
* Total back pain as measured by VAS (visual analog scale) ≥ 40 mm (0-100 mm) at baseline.
* Participants should have been on at least 2 different NSAIDs (non-steroidal anti-inflammatory drugs) at the highest recommended dose for at least 4 weeks in total prior to baseline with an inadequate response or failure to respond, or less if therapy had to be withdrawn due to intolerance, toxicity or contraindications.

Exclusion Criteria:

* Participants with radiographic evidence for sacroiliitis, grade ≥ 2 bilaterally or grade ≥ 3 unilaterally (radiological criterion according to the modified New York diagnostic criteria for AS) as assessed by central reader.
* Participants taking high potency opioid analgesics (e.g., methadone, hydromorphone, morphine).
* Previous exposure to secukinumab or any other biologic drug directly targeting IL-17 or IL-17 receptor or previous treatment with immunomodulatory biologic agents including those targeting TNFα (tumor necrosis factor α) (unless participants discontinued the treatment with TNFα inhibitor due to a reason other than efficacy \[primary or secondary lack of efficacy, inadequate response\] and only after appropriate wash-out period prior to baseline was observed).
* History of hypersensitivity to the study drug or its excipients or to drugs of similar chemical classes.
* Active ongoing inflammatory diseases other than nr-axSpA that might confound the evaluation of the benefit of secukinumab therapy, including uveitis.
* Active inflammatory bowel disease.
* History of ongoing, chronic or recurrent infectious disease or evidence of tuberculosis infection.

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