Study to Evaluate the Pharmacokinetics (PK), Safety and Tolerability up to 6 Years of Intravenous (i.v.) Secukinumab in Pediatric Participants With Juvenile Psoriatic Arthritis (JPsA).

Last Update: Apr 11, 2025
An Open-label, Multicenter Study to Evaluate Pharmacokinetics, Safety and Tolerability up to 6 Years of Intravenous Secukinumab Infusions in Pediatric Participants With Juvenile Psoriatic Arthritis
ClinicalTrials.gov Identifier:
NCT06751238
Novartis Reference Number:CAIN457G22101
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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 determine the PK, safety and tolerability of multiple doses of intravenous (i.v.) secukinumab in pediatric participants with JPsA This is a multicenter, open-label study with an optional treatment extension period to evaluate pharmacokinetics, safety and tolerability (up to 6 years) of i.v. secukinumab in pediatric patients with JPsA.

Condition
Juvenile Psoriatic Arthritis
Phase
Phase1
Overall Status
Recruiting
Number of Participants
20
Start Date
Jun 13, 2025
Completion Date
Apr 20, 2031
Gender
All
Age(s)
2 Years - 17 Years (Child)

Interventions

Biological

Secukinumab

Intravenous secukinumab

Eligibility Criteria

Key Inclusion Criteria:

* Participants parent's or legal representative(s) written informed consent and child's assent, if appropriate, must be obtained before any study related activity or assessment is performed. Of note, if the participant reaches age of consent (as per local law) during the study, they will also need to sign the corresponding study ICF (Informed Consent Form).
* Males and females ≥2 years old to \<18 years old at the time of screening.
* Confirmed diagnosis of JPsA according to the modified International League of Associations for Rheumatology (ILAR) classification criteria that must have occurred at least 6 months prior to screening.
* Active JPsA disease defined as ≥3 active joints (swollen or if not swollen must be both tender and limited range of motion) at baseline (BSL).
* Inadequate response (≥1 month) or intolerance to ≥1 Non-Steroidal Anti-Inflammatory Drug (NSAID) at screening.
* Inadequate response (≥2 months) or intolerance to ≥ 1 Disease Modifying Anti-Rheumatic Drug (DMARD) at screening.
* Concomitant use of the following second-line agents such as disease-modifying and/or immunosuppressive drugs to treat the JPsA will be allowed:

* Stable dose of methotrexate (MTX) (maximum of 20 mg/ m2 BSA/ week) for at least 4 weeks prior to the BSL visit, with folic/folinic acid supplementation (according to standard medical practice of the center).
* Stable dose of an oral corticosteroid (CS) at a prednisone equivalent dose of \<0.2 mg/kg/day or up to 10 mg/day maximum, whichever is less, for at least 7 days prior to BSL.
* Stable dose of no more than one NSAID for at least 1 week prior to BSL.

Key Exclusion Criteria:

* Participants with body weight less than 10 kg at screening.
* Use of other investigational drugs within 4 weeks or 5 half-lives of BSL, or until the expected pharmacodynamic effect has returned to BSL, whichever is longer.
* History of hypersensitivity to study drug or its excipients or to drugs of similar chemical classes.
* Participants with active inflammatory bowel disease or active uveitis at screening or BSL.
* Fulfilling diagnostic criteria for any International League of Associations for Rheumatology (ILAR) juvenile idiopathic arthritis (JIA) category other than JPsA at BSL.
* Participants treated with prohibited medication
* Participants taking any non-biologic DMARD at screening except for MTX.
* Any medical or psychiatric condition which, in the investigator's opinion, would preclude the participant from adhering to the protocol or completing the study per protocol.

Other inclusion/exclusion criteria may apply

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Recruiting

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If the location of your choosing does not feature any contact detail, please reach out using the information below.

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Source URL: *https://prod1.novartis.com/clinicaltrials/study/nct06751238*

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2. #trial-eligibility
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