# A Phase 3 Open-label Study to Assess the Efficacy, Safety, and Pharmacokinetics of;Subcutaneously Administered Ustekinumab in the Treatment of Moderate;to Severe Chronic Plaque Psoriasis in Pediatric Subjects greater than 6 to less than 12 Years of Age

Published: 01-12-2016
Last updated: 04-01-2025

Primary Objective• To evaluate the efficacy and safety of ustekinumab in pediatric subjects aged >=6 through =6 through =6 through =6 through

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| **Ethical review** | Approved WMO |
| **Status** | Completed |
| **Health condition type** | Epidermal and dermal conditions |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON45724

**Source**
ToetsingOnline

**Brief title**
CADMUS Jr. Psoriasis Study for Children

### Condition

- Epidermal and dermal conditions

**Synonym**
rash, skin disease

**Research involving**
Human

## Sponsors and support

**Primary sponsor:** Janssen-Cilag
**Source(s) of monetary or material Support:** Janssen

## Intervention

**Keyword:** Children, Psoriasis, Ustekinumab

## Outcome measures

### Primary outcome

Efficacy evaluations chosen for this study are consistent with applicable US and EU regulatory guidance and precedent established in previous studies of therapeutic biologic agents for the treatment of psoriasis. Patient-reported outcomes (PROs) chosen for this study are also consistent with clinically relevant measurements that are accepted in the medical literature for other studies in psoriasis and applicable US/EU regulatory guidance documents.

Psoriasis response evaluations include:

• Physician*s Global Assessment (PGA)

• Psoriasis Area and Severity Index (PASI)

• Children*s Dermatology Life Quality Index (CDLQI; PRO)

Given the open-label study design, PASI and PGA assessments will be performed by a blinded evaluator.

### Secondary outcome

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# Study description

### Background summary

STELARA® (ustekinumab) is a fully human immunoglobulin G1 kappa monoclonal antibody (mAb) that binds both human interleukin (IL)-12 and IL-23 via a common IL-12/23p40 subunit. Ustekinumab neutralizes the activities of IL-12 and IL-23 by preventing these cytokines from binding to the IL-12 receptor beta-1 receptor protein, which is expressed on the surface of immune cells. The first approval of ustekinumab for the treatment of adult patients with chronic moderate to severe plaque psoriasis occurred in Canada (12 December 2008) and was based primarily on data from 2 global Phase 3 pivotal studies (C0743T08 [PHOENIX 1] and C0743T09 [PHOENIX 2]), comprising 1,996 subjects. Both studies had long-term extensions for up to 5 years. Ustekinumab was subsequently approved in numerous other countries in North America, Europe, South America, and the Asia-Pacific region, for the treatment of adult patients with chronic moderate to severe plaque psoriasis and/or psoriatic arthritis (PsA). Ustekinumab has also been approved for the treatment of pediatric moderate to severe psoriasis in patients >=12 years to <18 years in Europe and other countries, based primarily on data from the completed Phase 3 CADMUS study. Extensive postmarketing experience also supports the favorable safety profile of ustekinumab established to date.

### Study objective

Primary Objective
• To evaluate the efficacy and safety of ustekinumab in pediatric subjects aged >=6 through <12 years with moderate to severe chronic plaque psoriasis.
Major Secondary Objectives
• To evaluate the pharmacokinetics (PK) of ustekinumab in pediatric subjects aged >=6 through <12 years with moderate to severe chronic plaque psoriasis.
• Evaluate the effect of ustekinumab on the dermatologic health-related quality of life in pediatric subjects aged >=6 through <12 years with moderate to severe chronic plaque psoriasis.
• Evaluate the immunogenicity of ustekinumab in pediatric subjects aged >=6 through <12 years with moderate to severe chronic plaque psoriasis.

### Study design

This is an open-label multicenter study of ustekinumab in pediatric subjects >=6 to <12 years of age with moderate to severe chronic plaque psoriasis. At least 40 subjects will receive a weight-based dose of ustekinumab administered subcutaneously at Weeks 0 and 4 followed by dose administrations every 12 weeks (q12w) through Week 40. Subject weight will be measured at each visit and the dose of ustekinumab will be adjusted accordingly. Visits will be every 4 weeks

through Week 16, then q12w through Week 52. Efficacy assessments will be collected through Week 52. Subjects will have a final safety telephone follow-up at Week 56. A single database lock will occur at Week 56.
All assessments will be performed according to the Time and Events Schedule. Unblinded safety data will be routinely evaluated by the study medical monitor. The study will end when the last subject completes the Week 56 visit.

**Intervention**

All subjects enrolled in the study will receive ustekinumab at Weeks 0 and 4 followed by q12w dosing with the last dose at Week 40. Subject weight will be measured at each visit and the dose of ustekinumab will be adjusted accordingly. Subjects will receive 1 of the following dose levels:
• Weight <60 kg: 0.75 mg/kg
• Weight >=60 kg to <=100 kg: 45 mg
• Weight >100 kg: 90 mg

**Study burden and risks**

The expected therapeutic effect (therapy is already approved for persons above 12 years) justifies the burden and risks for the participants.

# Contacts

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# Trial sites

## Listed location countries

Netherlands

# Eligibility criteria

**Age**
Children (2-11 years)

## Inclusion criteria

- Participants who have a diagnosis of plaque-type psoriasis with or without psoriatic arthritis (PsA) for at least 6 months prior to first administration of study drug, with widespread lesions defined by Psoriasis Area and Severity;Index score (PASI) greater than or equal to 12, Physician*s Global Assessment (PGA) greater than or equal to 3, and involved body surface area (BSA)greater than or equal to 10 percent (%) ;- Participants who are candidates for phototherapy or systemic treatment of psoriasis (either naive or history of previous treatment) or have psoriasis considered by the investigator as poorly controlled with topical therapy after an adequate dose and duration of therapy ;- Participants who are considered eligible according to the protocol defined tuberculosis (TB) screening criteria;- Participants must have positive protective antibody titers to varicella and measles prior to the first administration of study drug. In the absence of positive protective antibody titers, the participant must have documentation of age-appropriate vaccination for varicella and/or measles (that includes both doses of each vaccine) or verification of past varicella and/or measles infection documented by a health care provider ;- Participants must agree not to receive a live virus or live bacterial vaccination at least 2 weeks (or longer as indicated in the package insert of the relevant vaccine) prior to the first administration of study drug, during the study, or within 15 weeks after the last administration of study drug;- Participants must agree not to receive a Bacille Calmette-Guerin (BCG) vaccination within 12 months of screening, during the study, or within 12 months after the last administration of study drug

## Exclusion criteria

- Participants who currently have nonplaque forms of psoriasis ;- Have received any systemic immunosuppressants within 4 weeks of the first administration of study drug;- Have received any biologic agent (example ENBREL, HUMIRA) within the previous 3 months or 5 times the t1/2 of the agent, whichever is longer;- Have a history of chronic or recurrent infectious disease;- Have a history of latent or active granulomatous infection;- Have any known malignancy or have a history of malignancy;- Have a known history of lymphoproliferative disease, including lymphoma, or signs and symptoms suggestive of possible lymphoproliferative disease

# Study design

## Design

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| Study phase: | 3 |
| Study type: | Interventional |
| Masking: | Open (masking not used) |
| Control: | Uncontrolled |
| Primary purpose: | Treatment |

## Recruitment

NL

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|---|---|
| Recruitment status: | Completed |
| Start date (anticipated): | 11-07-2017 |
| Enrollment: | 1 |
| Type: | Actual |

## Medical products/devices used

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|---|---|
| Product type: | Medicine |
| Brand name: | Stelara |
| Generic name: | Ustekinimab |
| Registration: | Yes - NL intended use |

# Ethics review

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| Approved WMO Date: | 01-12-2016 |
| Application type: | First submission |
| Review commission: | CMO regio Arnhem-Nijmegen (Nijmegen) |
| Approved WMO Date: | 15-05-2017 |
| Application type: | First submission |
| Review commission: | CMO regio Arnhem-Nijmegen (Nijmegen) |
| Approved WMO Date: | 07-08-2017 |
| Application type: | Amendment |
| Review commission: | CMO regio Arnhem-Nijmegen (Nijmegen) |
| Approved WMO | |

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| Date: | 10-08-2017 |
| Application type: | Amendment |
| Review commission: | CMO regio Arnhem-Nijmegen (Nijmegen) |
| Approved WMO Date: | 04-10-2017 |
| Application type: | Amendment |
| Review commission: | CMO regio Arnhem-Nijmegen (Nijmegen) |
| Approved WMO Date: | 01-02-2018 |
| Application type: | Amendment |
| Review commission: | CMO regio Arnhem-Nijmegen (Nijmegen) |
| Approved WMO Date: | 11-07-2018 |
| Application type: | Amendment |
| Review commission: | CMO regio Arnhem-Nijmegen (Nijmegen) |
| Approved WMO Date: | 08-05-2019 |
| Application type: | Amendment |
| Review commission: | CMO regio Arnhem-Nijmegen (Nijmegen) |
| Approved WMO Date: | 15-04-2020 |
| Application type: | Amendment |
| Review commission: | CMO regio Arnhem-Nijmegen (Nijmegen) |

## Study registrations

### Followed up by the following (possibly more current) registration

No registrations found.

### Other (possibly less up-to-date) registrations in this register

No registrations found.

## In other registers

| Register | ID |
|---|---|
| Other | 2016-000121-40 |
| EudraCT | EUCTR2016-000121-40-NL |
| CCMO | NL59546.091.16 |

# Study results

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|---|---|
| Date completed: | 31-08-2020 |
| Results posted: | 18-10-2021 |
| Actual enrolment: | 1 |

**First publication**
16-04-2021

**URL result**
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