# A Phase 3b, open-label treatment extension study of upadacitinib for the treatment of adult subjects with moderate to severe atopic dermatitis who completed treatment in Study M16-046

Published: 17-03-2020
Last updated: 25-03-2025

To assess long-term safety, tolerability and efficacy of upadacitinib in adult subjects with moderate to severe atopic dermatitis who successfully completed treatment in the M16-046 study. Efficacy will be evaluated through Week 52, and safety and...

| | |
|---|---|
| **Ethical review** | Approved WMO |
| **Status** | Completed |
| **Health condition type** | Autoimmune disorders |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON55265

**Source**
ToetsingOnline

**Brief title**
M19-850

### Condition

- Autoimmune disorders
- Epidermal and dermal conditions

**Synonym**
Atopic Dermatitis, Eczema

**Research involving**
Human

## Sponsors and support

**Primary sponsor:** AbbVie Deutschland GmbH & Co. KG
**Source(s) of monetary or material Support:** AbbVie

## Intervention

**Keyword:** Adults, Atopic dermatitis, Upadacitinib

## Outcome measures

### Primary outcome

Treatment emergent adverse events (TEAEs), serious adverse events (SAEs), adverse events (AEs) of special interest (AESI), AEs leading to discontinuation of study drug; vital signs, laboratory tests, and physical examination findings.

### Secondary outcome

- Change and percent change from Baseline in worst pruritus numerical rating scale (NRS)

- Change and percent change from Baseline in EASI

- Proportion of subjects achieving EASI 75/90/100

- Evaluation of known and/or novel disease-related or drug-related biomarkers

# Study description

### Background summary

Atopic dermatitis (AD) is a skin condition that may cause a rash and itching due to inflammation of the skin. Therapies spread over the skin may not be enough to control AD in patients who require systemic anti-inflammatory

treatments taken by mouth or injection through the skin or vein.

### Study objective

To assess long-term safety, tolerability and efficacy of upadacitinib in adult subjects with moderate to severe atopic dermatitis who successfully completed treatment in the M16-046 study. Efficacy will be evaluated through Week 52, and safety and tolerability of upadacitinib will be evaluated until the end of the study.

### Study design

Open label, single group assignment.

### Intervention

The study consists of a baseline visit (Week 24 [last on-treatment visit] of M16-046 study)and a 52-week open-label treatment period. The treatment period can be extended until regulatory approval and/or applicable local reimbursement approval of the study drug. At the end of the study a follow-up visit (or phone call if a visit is not possible) will be done 30 days after the last dose of upadacitinib.

### Study burden and risks

The effect of treatment on the disease will be checked by performing dermatologic assessments, blood tests, checking for side effects, and completing questionnaires. Safety evaluations will occur throughout the study.

## Contacts

**Public**
AbbVie Deutschland GmbH & Co. KG

Knollstrasse 50
Ludwigshafen 67061
DE
**Scientific**
AbbVie Deutschland GmbH & Co. KG

Knollstrasse 50
Ludwigshafen 67061
DE

# Trial sites

## Listed location countries

Netherlands

# Eligibility criteria

**Age**
Adults (18-64 years)
Elderly (65 years and older)

## Inclusion criteria

• Subjects should have successfully completed treatment in the M16-046 study, without developing any permanent discontinuation criteria.
• Subject is judged to be in general good health (other than AD) as determined by the Principal Investigator and remains eligible as per the criteria for the M16-046 study to continue treatment in the long term extension study.

## Exclusion criteria

• Requirement of prohibited medications during the study treatment or would interfere with appropriate assessment of atopic dermatitis lesions
• Female subject who is pregnant, breastfeeding, or considering pregnancy during the study

# Study design

## Design

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

## Recruitment

NL

| | |
|---|---|
| Recruitment status: | Completed |
| Start date (anticipated): | 29-05-2020 |
| Enrollment: | 15 |
| Type: | Actual |

## Medical products/devices used

| | |
|---|---|
| Product type: | Medicine |
| Brand name: | Rinvoq |
| Generic name: | Upadacitinib |
| Registration: | Yes - NL outside intended use |

# Ethics review

| | |
|---|---|
| Approved WMO Date: | 17-03-2020 |
| Application type: | First submission |
| Review commission: | BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen) |

| | |
|---|---|
| Approved WMO Date: | 16-04-2020 |
| Application type: | First submission |
| Review commission: | BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen) |

| | |
|---|---|
| Approved WMO Date: | 26-06-2020 |
| Application type: | Amendment |
| Review commission: | BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen) |

| | |
|---|---|
| Approved WMO Date: | 07-07-2020 |
| Application type: | Amendment |
| Review commission: | BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen) |

Approved WMO

| | |
|---|---|
| Date: | 05-10-2020 |
| Application type: | Amendment |
| Review commission: | BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen) |
| Approved WMO Date: | 22-02-2021 |
| Application type: | Amendment |
| Review commission: | BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen) |
| Approved WMO Date: | 17-03-2021 |
| Application type: | Amendment |
| Review commission: | BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen) |
| Approved WMO Date: | 22-03-2021 |
| Application type: | Amendment |
| Review commission: | BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen) |
| Approved WMO Date: | 17-09-2021 |
| Application type: | Amendment |
| Review commission: | BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen) |
| Approved WMO Date: | 19-10-2022 |
| Application type: | Amendment |
| Review commission: | BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen) |
| Approved WMO Date: | 08-11-2023 |
| Application type: | Amendment |
| Review commission: | BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen) |

## 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 |
|---|---|
| EudraCT | EUCTR2019-001227-12-NL |
| ClinicalTrials.gov | NCT04195698 |
| CCMO | NL72873.056.20 |

# Study results

Date completed: 12-05-2022

Results posted: 11-09-2024

**First publication**
09-08-2024

**URL result**
URL
Type
int
Naam
M2.2 Samenvatting voor de leek
URL

**Internal documents**
File