A Phase 3b/4 Randomized, Blinded, Treat-to-Target and Dose-Flexibility Study of Upadacitinib in Adult Subjects with Moderate to Severe Atopic Dermatitis

Published: 09-08-2022
Last updated: 16-11-2024

This study has been transitioned to CTIS with ID 2023-504869-23-00 check the CTIS register for the current data. 1. Sub-Study 1 (SS1): The primary study objective for SS1 is to evaluate the efficacy and safety of dose escalation to upadacitinib 30...

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

Summary

ID

NL-OMON53671

Source
ToetsingOnline

Brief title
M22-000

Condition

- Epidermal and dermal conditions

Synonym
Atopic dermatitis, eczema

Research involving
Human

Sponsors and support

Primary sponsor: AbbVie B.V.
Source(s) of monetary or material Support: AbbVie

Intervention

Keyword: Atopic dermatitis, Dose escalation, Dose reduction, Upadacitinib

Outcome measures

Primary outcome

The primary endpoints are:

- Achievement of EASI 90 at Week 24.

Secondary outcome

The secondary endpoints are: - Achievement of EASI 75 / 100 at Week 24. - Achievement of EASI 75 / 90 / 100 at Week 12. - Achievement of EASI 90 and Worst Pruritus NRS of 0 or 1 for subjects with Worst Pruritus NRS > 1 at Baseline at Week 12 and week 24. - Achievement of vIGA-AD of 0 or 1 at Week 12. - Achievement of vIGA-AD of 0 or 1 at Week 24. - Achievement of an improvement (reduction) in Worst Pruritus (NRS >= 4 for subjects with Worst Pruritus NRS >= 4 at Baseline at Week 12. - Achievement of an improvement (reduction) in Worst Pruritus NRS >= 4 for subjects with Worst Pruritus NRS >= 4 at Baseline at Week 24. - Achievement of Worst Pruritus NRS of 0 or 1 for subjects with Worst Pruritus NRS > 1 at Baseline at Week 12. - Achievement of Worst Pruritus NRS of 0 or 1 for subjects with Worst Pruritus NRS > 1 at Baseline at Week 24. - Achievement of an improvement (reduction) from Baseline in DLQI >= 4 for subjects with DLQI >= 4 at Baseline at Week 12. - Achievement of an improvement (reduction) from Baseline in DLQI >= 4 for subjects with DLQI >= 4 at Baseline at

Week 24. - Achievement of DLQI 0/1 for subjects with DLQI > 1 at Baseline at

Week 12. - Achievement of DLQI 0/1 for subjects with DLQI > 1 at Baseline at

Week 24.

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 the AD in trial participants who require systemic anti-inflammatory treatment. This study evaluates the dosing flexibility of upadacitinib in adult participants with moderate to severe AD. Adverse events and change in the disease activity will be assessed.

Study objective

This study has been transitioned to CTIS with ID 2023-504869-23-00 check the CTIS register for the current data.

1. Sub-Study 1 (SS1): The primary study objective for SS1 is to evaluate the efficacy and safety of dose escalation to upadacitinib 30 mg QD in subjects who do not achieve Eczema Area and Severity Index (EASI) 90 on upadacitinib 15 mg QD after 12 weeks.
2. Sub-Study 2 (SS2): The primary study objective for SS2 is to evaluate the efficacy and safety of dose reduction to upadacitinib 15 mg QD in subjects who achieve EASI 90 on upadacitinib 30 mg QD after 12 weeks. No hypothesis testing will be performed in this study.

Study design

Randomized, double-blind, sequential group study

Intervention

The study is comprised of a 12-week double-blind period, followed by a 12-week single-blind period. Participants will receive upadacitinib oral tablets once daily for up to 24 weeks.

Study burden and risks

There may be higher treatment burden for participants in this trial compared to their standard of care (due to study procedures). Participants will attend regular visits during the study at a hospital or clinic. The effect of the treatment will be checked by medical assessments, blood tests, checking for side effects and completing questionnaires.

Contacts

Public
AbbVie B.V.

Wegalaan 9
Hoofddorp 2132 JD
NL
Scientific
AbbVie B.V.

Wegalaan 9
Hoofddorp 2132 JD
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

- Male or female subjects >= 18 and < 65 years of age at the screening visit
- Chronic AD with onset of symptoms at least 3 years prior to Baseline and subject meets Hanifin and Rajka criteria - Candidate for systemic treatment

Exclusion criteria

- Prior exposure to any JAK inhibitor
- Unable or unwilling to discontinue current AD treatments prior to the study
- Requirement of prohibited medications during the study treatment
- Female subject who is pregnant, breastfeeding, or considering pregnancy during the study

Study design

Design

Study phase:	4
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	21-09-2023
Enrollment:	14
Type:	Actual

Medical products/devices used

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

Ethics review

Approved WMO Date:	09-08-2022
Application type:	First submission
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	24-10-2022
Application type:	First submission
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	14-11-2022
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	21-05-2023
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	26-06-2023
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)

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
EU-CTR	CTIS2023-504869-23-00
EudraCT	EUCTR2022-000434-42-NL
CCMO	NL81845.028.22