An Active Surveillance Study to Monitor the Safety of Abrocitinib Among Real-World Patients with Atopic Dermatitis (AD) in the European Union (EU)

First published: 30/10/2024

Last updated: 07/01/2025

Study Ongoing

Administrative details

EU PAS number

EUPAS1000000282

Study ID

1000000282

DARWIN EU® study

No

Study countries

- ☐ Denmark
- ☐ France
- ☐ Sweden

Study description

The primary objective of the study is to estimate the IRs of the safety events of interest among patients with AD receiving abrocitinib and patients with AD receiving biologic and/or non biologic (non-JAKi) chronic systemic treatments for AD (herein referred to as “comparator treatments”) in a real-world setting.
The following are the safety events of interest for this study:

- VTE
- HZ
- Serious infections and opportunistic infections
- Rhabdomyolysis
- GI perforation
- MACE
- Fractures
- Malignancy excluding NMSC
- NMSC
- All-cause mortality
- Height as a measure of impaired bone growth in adolescents (Denmark only).

This will be a longitudinal, register-based, non-interventional post-authorisation safety cohort study using routinely collected (secondary) population-based data.

Study status

Ongoing

Research institutions and networks

Institutions

Aarhus University & Aarhus University Hospital DEPARTMENT OF CLINICAL EPIDEMIOLOGY

Denmark

First published: 20/07/2021

Last updated: 02/04/2024

Institution | Educational Institution | ENCePP partner

Centre for Pharmacoepidemiology, Karolinska Institutet (CPE-KI)

Sweden

First published: 24/03/2010

Last updated: 23/04/2024

Institution | Educational Institution | Laboratory/Research/Testing facility | Not-for-profit | ENCePP partner

Bordeaux PharmacoEpi, University of Bordeaux

France

First published: 07/02/2023

Last updated: 08/02/2023

Institution | Educational Institution | Hospital/Clinic/Other health care facility | Not-for-profit | ENCePP partner

Pfizer

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Networks

The SIGMA Consortium (SIGMA)

- [ ] Denmark
- [ ] European Union
- [ ] France
- [ ] Germany
- [ ] Italy
- [ ] Netherlands
- [ ] Norway
- [ ] Spain
- [ ] Sweden
- [ ] United Kingdom

First published: 10/02/2013

Last updated: 16/12/2024

Network ENCePP partner

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Henrik Toft Sorensen

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 22/06/2022

Actual: 22/06/2022

Study start date

Planned: 31/12/2024

Actual: 31/12/2024

Data analysis start date

Planned: 16/05/2034

Date of interim report, if expected

Planned: 15/11/2029

Date of final study report
Planned: 15/11/2034

Sources of funding

- Pharmaceutical company and other private sector

Study protocol

B7451084_ABROCITINIB PROTOCOL AMENDMENT 1_23MAY2024.pdf(1.6 MB)

Regulatory

Was the study required by a regulatory body?

Yes

Is the study required by a Risk Management Plan (RMP)?

EU RMP category 3 (required)

Other study registration identification numbers and links

B7451084

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Safety study (incl. comparative)

Study design:

This will be a longitudinal, register-based, non-interventional post-authorisation safety cohort study using routinely collected (secondary) population-based data.

Main study objective:

The primary objective of the study is to estimate the incidence rates (IRs) of safety events of interest among patients with AD receiving abrocitinib and patients with AD receiving biologic and/or non-biologic (non- Janus Kinase inhibitor [non JAKi]) chronic systemic treatments for AD (comparator treatments) in a real-world setting.

An exploratory objective of this study is to compare the risk of the safety events of interest among patients with AD receiving abrocitinib and patients with AD receiving dupilumab or other anti-IL-4/13 monoclonal antibodies

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Name of medicine

CIBINQO

Study drug International non-proprietary name (INN) or common name

ABROCITINIB

Anatomical Therapeutic Chemical (ATC) code

(D11AH08) abrocitinib

abrocitinib

Population studied

Short description of the study population

The study population will include patients with AD receiving abrocitinib or a comparator treatment as recorded in the participating databases in Denmark, France, and Sweden.

Study design details

Setting

The study population will include patients with AD receiving abrocitinib or a comparator treatment as recorded in the participating databases in Denmark, France, and Sweden following the authorization of abrocitinib on 09 December 2021, through to 31 December 2031.

All participating countries have universal healthcare, which contributes routinely collected secondary data to the participating nationwide databases.

Comparators

The comparator treatments include non-biologic and biologic treatments.

Outcomes

The following are the safety events of interest in relation to the primary objective:

• Venous thromboembolism (VTE)
• Herpes zoster (HZ)
• Serious infections and opportunistic infections
• Rhabdomyolysis
• Gastrointestinal (GI) perforation
• Major adverse cardiovascular events (MACE)
• Fractures
• Malignancy excluding non-melanoma skin cancer (NMSC)
• NMSC
• All-cause mortality
• Height as a measure of impaired bone growth in adolescents (Denmark only)

Data analysis plan

Distributions of the baseline characteristics of patients with AD will be reported by exposure cohort, using appropriate summary statistics: counts and proportions for categorical variables, and mean and standard deviations (or median with interquartile range (IQR), where appropriate) for continuous variables.

The primary analysis will comprise estimation of IRs with 95% CIs for the safety events of interest (except the adolescent height metrics, which will be reported using means, medians or percentiles as appropriate) documented among patients with AD initiating abrocitinib and patients with AD receiving comparator treatments.

Data management

ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

Data sources

Data source(s)

Danish registries (access/analysis)

Système National des Données de Santé (French national health system main database)

Sweden National Prescribed Drugs Register / Läkemedelsregistret

Sweden National Cancer Register / Cancerregistret

Swedish Cause of Death Register

Landspatientregisteret (National Patient Register)

Data source(s), other

Total Population Register

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No