A Prospective Active Surveillance Study to Monitor Growth, Development, and Maturation Among Adolescents with Atopic Dermatitis Exposed to Abrocitinib

First published: 14/04/2025 Last updated: 22/04/2025



# Administrative details

#### **EU PAS number**

EUPAS100000515

#### **Study ID**

100000515

#### DARWIN EU® study

No

#### Study countries

Canada

European Union

United States

#### **Study description**

This is a prospective observational cohort study of adolescents with moderateto-severe atopic dermatitis (AD) who receive abrocitinib or another advanced systemic therapy approved in adolescents for the treatment of moderate-to-severe AD.

#### Study status

Planned

# Research institutions and networks

# Institutions

## Pfizer

First published: 01/02/2024

Last updated: 01/02/2024

Institution

CorEvitas

## Networks

International Adolescent Atopic Dermatitis Registry

# Contact details

#### Study institution contact

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Study contact

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Primary lead investigator Heather Ward

Primary lead investigator

# Study timelines

#### Date when funding contract was signed

Actual: 24/05/2023

#### Study start date

Planned: 30/09/2025

#### Data analysis start date

Planned: 01/02/2036

#### Date of interim report, if expected

Planned: 30/04/2030

#### **Date of final study report** Planned: 31/07/2036

## Sources of funding

• Pharmaceutical company and other private sector

## More details on funding

Pfizer 100%

# Study protocol

B7451120\_ABROCITINIB INITIAL PROTOCOL\_V1.0\_19NOV2024.pdf(633.35 KB)

# 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

B7451120

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)

#### Data collection methods:

Secondary use of data

#### Study design:

This will be a prospective observational cohort study of adolescents with moderate-to-severe AD who receive abrocitinib or another advanced systemic therapy approved in adolescents for the treatment of moderate-to-severe AD.

#### Main study objective:

The primary objectives are:

Among adolescent participants with AD who are treated with abrocitinib and, separately, among adolescent participants with AD unexposed to abrocitinib and receiving advanced systemic treatments, to:

- Describe physical growth and development metrics;
- Describe sexual maturation metrics;

- Describe the incidence of bone fractures, stratified by abrocitinib dosage (100 mg and 200 mg QD).

# 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

#### Medical condition to be studied

Erythrodermic atopic dermatitis

# Population studied

#### Short description of the study population

12-<16 -year-olds with moderate-to-severe AD in the US, Canada, and Europe enrolled in the CorEvitas International Adolescent AD Registry.

Participants are followed until they exit the registry or reach 18 years of age (i.e., the participant's 18th birthday), whichever comes first.

The study period will include registry data collected from 21 March 2024 until 31 December 2035.

#### Age groups

Adolescents (12 to < 18 years)

#### Estimated number of subjects

700

# Study design details

#### Setting

The CorEvitas International Adolescent AD Registry has identified dermatological clinics throughout Europe, the US, and Canada, that have a high volume of treated adolescent patients with AD are identified by CorEvitas and asked to participate in the CorEvitas International Adolescent AD Registry. Data collection occurs via CorEvitas registry questionnaires at the time of enrolment and approximately every 6 months thereafter for the duration of a participant's registry participation.

If there is a change in AD treatment, early visit follow-up questionnaires may also be completed. Additionally, the occurrence of adverse events or registry protocol-defined safety events of interest are actively assessed by participating CorEvitas site investigators at each registry visit and recorded in the registry questionnaires.

CorEvitas' registry sites are trained by CorEvitas on the registry protocol, data collection, and reporting requirements, including the submission of supporting medical documentation (ie, relevant primary source medical records), for such events at regularly scheduled follow-up visits and when identified between registry visits.

#### Comparators

The comparator cohort will comprise advanced systemic therapies that are approved in adolescents for moderate-to-severe AD, including dupilumab, baricitinib, lebrikizumab, tralokinumab, and upadacitinib. The exposure for the comparator cohort will include biologic or other nonbiologic advanced systemic medications approved for the treatment of moderate-to-severe AD in adolescents in the EU at the time of registry enrollment. If new systemic therapies are approved for the treatment of moderate-to-severe AD in adolescents during the study period, subsequent exposures to the new approved systemic therapies will also be included in the comparator cohort.

Drug exposure is reported by the treating healthcare provider at enrolment into the registry, and any changes to

exposure are reported at follow-up visits.

#### Outcomes

The primary outcomes are physical growth and development, sexual maturation, Tanner staging, age at peak height velocity (aPHV), and bone fractures. These outcomes are described in more detail in the study protocol.

#### Data analysis plan

The population of participants in this study will be characterised with respect to demographics, clinical and disease characteristics, and treatment history using descriptive statistics by exposure cohort as defined in protocol section 9.3.1. All pre-defined adverse events/reactions collected in the registry (protocol Appendix Table A) will be tabulated as counts and rates for each exposure cohort in the interim safety analysis and in the final study report. Follow-up time per exposure episode and baseline participant characteristics, including the key variables listed in protocol Section 9.3.3, will be presented by exposure cohort. Continuous variables will be summarised using descriptive

statistics including mean, median, standard deviation, interquartile range (IQR), minimum, and maximum.

Categorical variables will be summarised using frequency and percent. Standardised differences will be used to compare baseline characteristics between cohorts. An absolute standardised value greater than 0.1 would indicate a notable difference between participants who receive abrocitinib versus those in the comparator cohort.

The primary and exploratory analyses described below will be performed separately by region, among participants who reside in NA and among participants who reside in EUR. The exploratory analysis will be conducted separately by region if sample size allows.

## Data management

## Data sources

#### Data source(s), other

CorEvitas International Adolescent AD Registry

#### Data sources (types)

Disease registry

# 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

Unknown