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: 14/04/2025

Study Planned

Administrative details

PURI

https://redirect.ema.europa.eu/resource/1000000515

EU PAS number

EUPAS1000000515

Study ID

1000000515

DARWIN EU® study

No

Study countries

- [ ] Canada
- [ ] European Union
- [ ] United States

Study description

This is a prospective observational cohort study of adolescents with moderate-to-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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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%

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 non-biologic 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