A Prospective, Observational Study to Assess the Long-Term Safety of Abrocitinib Treatment in Adult Patients with Moderate-to-Severe Atopic Dermatitis

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Study Planned

Administrative details

EU PAS number

EUPAS1000000420

Study ID

1000000420

DARWIN EU® study

No

Study countries

European Union

United States

Study description

As part of the abrocitinib pharmacovigilance plan, a non-interventional study (NIS) using real-world data from routine clinical care is being conducted to actively monitor safety events of interest associated with exposure to abrocitinib in the post-approval setting. The study will be designed to estimate the incidence of total malignancies excluding nonmelanoma skin cancer (NMSC), but including lymphoma, lung cancer, and other malignancies, NMSC, MACE, serious infections, opportunistic infections, herpes zoster (HZ), retinal detachment, thrombosis (including deep venous thrombosis, pulmonary embolism and arterial thrombosis), and hepatotoxicity including drug induced liver injury (DILI) in abrocitinib-treated patients and patients treated with comparator biologic and nonbiologic (non-JAKi) chronic systemic treatments for atopic dermatitis.

Study status

Planned

Research institutions and networks

Institutions

Pfizer

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Institution

CorEvitas

Contact details

Study institution contact

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Primary lead investigator

Sampada Gandhi

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 14/04/2023

Actual: 14/04/2023

Study start date

Planned: 01/06/2028

Date of interim report, if expected

Planned: 15/12/2028

Date of final study report

Planned: 31/10/2034

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Pfizer 100%

Study protocol

B7451097_ABROCITINIB PROTOCOL_V1.0_16MAR2023.pdf (2.65 MB)

Regulatory

Was the study required by a regulatory body?

Yes

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

Non-EU RMP only

Other study registration identification numbers and links

B7451097

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 is a prospective, observational cohort study of adult patients (≥ 18 years) receiving abrocitinib or comparator biologic or non-biologic (non-JAKi) chronic systemic treatments for atopic dermatitis (AD).

Main study objective:

The main objective is to estimate the incidence rates (IR) of safety events of interest including malignancies excluding NMSC, NMSC, MACE, serious infections, opportunistic infections, HZ, retinal detachment, thrombosis (including deep venous thrombosis, pulmonary embolism, and arterial thrombosis), and hepatotoxicity (including
DILI) in adults with AD who are exposed to abrocitinib during the course of routine clinical care. To contextualize the results, the study will also include patients receiving comparator biologic and non-biologic (non-JAKi) chronic systemic treatments for AD.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name

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

Dermatitis atopic

Population studied

Short description of the study population

The study will use real-world data (RWD) collected in the context of routine clinical care from the CorEvitas AD Registry, which is an established, prospective, multicenter, observational registry for adult patients in the US and Canada.

Age groups

- **Adult and elderly population (≥18 years)**

Study design details

Setting

The CorEvitas AD registry currently enrolls a broad eligible population for participation in the registry. Though the registry is open to patients initiating or having recently (within 12 months) initiated a biologic or systemic therapy for AD, approximately 90% of patients enrolling into the registry are being treated with a biologic, with approximately 10% currently treated with a non-biologic systemic treatment.

Comparators

The comparator group will include exposures to any biologic or non-biologic (non-JAKi) chronic systemic therapy used for the treatment of AD, including new therapies as they become approved.

Outcomes

Total malignancies excluding nonmelanoma skin cancer (NMSC), but including lymphoma, lung cancer, and other
malignancies, NMSC, MACE, serious infections, opportunistic infections, herpes zoster (HZ), retinal detachment, thrombosis (including deep venous thrombosis, pulmonary embolism and arterial thrombosis), and hepatotoxicity including drug induced liver injury (DILI).

Data analysis plan

All analyses will characterize exposure time into an abrocitinib group and a comparator group. For each grouping, the baseline will be characterized by treatment exposure group with respect to demographic, disease activity and disease severity, validated patient-reported outcome measures (e.g., DLQI), and history of safety events of special interest using descriptive statistics. Mean, median, minimum, and maximum values, interquartile range (IQR), and standard deviation will be provided for continuous variables when performing descriptive analysis of continuous data. Numbers and percentages will be

provided for dichotomous and polychotomous variables when performing summary analysis of categorical data.
Except the sensitivity analysis using propensity-score matching method, all other analyses will employ inverse probability of treatment weighting (IPTW) as the primary analytic approach to address confounding by indication (channeling bias, notably including line of therapy) and preserve sample size. For all primary analyses, only the first event of each individual event type will be evaluated; the incident event will end the risk period for that
event type.
Additionally, for events where there is adequate power to compare the risk between abrocitinib and comparators, multivariable Cox proportional hazards models will be fit to compare risk of the event between abrocitinib and the comparator groups.
Detailed methodology for summary and statistical analyses of data collected in this study will be documented in a statistical analysis plan (SAP), which will be dated, filed, and maintained by the sponsor. The SAP may modify the plans outlined in the protocol; any major modifications of definitions for the main safety events of interest or their analyses would be reflected in a protocol amendment.

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), other

CorEvitas Atopic Dermatitis 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

No