A Post-Authorization Safety Study to Evaluate the Safety of Abrocitinib Exposure During Pregnancy in United States Healthcare Databases

First published: 04/04/2024

Last updated: 19/04/2024

Study Ongoing

Administrative details

EU PAS number

EUPAS1000000096

Study ID

1000000096

DARWIN EU® study

No

Study countries

☐ United States

Study description

This US population-based, non-interventional, cohort study will evaluate the risk of adverse pregnancy and infant outcomes among women with moderate-to-severe AD who are exposed to abrocitinib during pregnancy compared to those unexposed during pregnancy. Pregnancies with start dates occurring during the period 14 January 2022 to Q4 2025, and infants born to the women, will be included. The main outcome of interest will be MCMs. Additional outcomes of interest include other adverse infant outcomes (preterm birth, SGA) and pregnancy outcomes (stillbirth, spontaneous abortion).

Study status

Ongoing

Research institutions and networks

Institutions

Pfizer

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Harvard Pilgrim Health Care Institute

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Jenny Sun

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 07/09/2022

Actual: 07/09/2022

Study start date

Planned: 31/12/2022

Actual: 31/12/2022

Data analysis start date

Planned: 01/03/2024

Actual: 17/04/2024

Date of final study report

Planned: 30/06/2028

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Pfizer

Study protocol

B7451098_ABROCITINIB UPDATED PROTOCOL_18NOV2022_Redacted.pdf (2.88 MB)

Regulatory

Was the study required by a regulatory body?

Yes

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

Not applicable

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Safety study (incl. comparative)

Data collection methods:

Secondary use of data

Study design:

This US population-based, non-interventional, cohort study will evaluate the risk of adverse pregnancy and infant outcomes among women with moderate-to-severe AD who are exposed to abrocitinib during pregnancy compared to those unexposed during pregnancy.

Main study objective:

To describe and compare the adverse pregnancy and infant outcomes among women with moderate-to-severe AD who are exposed to abrocitinib during pregnancy and women with moderate-to-severe AD who are not exposed to abrocitinib.

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

Additional medical condition(s)

Moderate-to-severe atopic dermatitis (AD)

Population studied

Short description of the study population

The study population will include singleton pregnancies among women 12 to 49 years of age diagnosed with moderate-to-severe AD who are members of participating Sentinel Data Partners (DPs).

Age groups

- Adolescents (12 to < 18 years)
- Adults (18 to < 46 years)
- Adults (46 to < 65 years)

Special population of interest

Pregnant women

Study design details

Setting

The study will be conducted using data provided by US Data Partners in the FDA's Sentinel System. The study population will include singleton pregnancies among women 12 to 49 years of age diagnosed with moderate-to-severe AD who are members of participating Sentinel Data Partners (DPs).

Outcomes

The main outcome of interest will be MCMs. Additional outcomes of interest include other adverse infant outcomes (preterm birth, SGA) and pregnancy outcomes (stillbirth, spontaneous abortion).

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

Sentinel Data Partners

Data sources (types)

Administrative healthcare records (e.g., claims)

Use of a Common Data Model (CDM)

CDM mapping

Yes

CDM Mappings

CDM name

Sentinel

CDM website

https://www.sentinelinitiative.org/methods-Data-tools/sentinel-common-Data-model

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

Unknown