CIBINQO™ Pregnancy Registry: An Observational Study of the Safety of Abrocitinib Exposure in Pregnant Women and Their Offspring

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Study | Planned

Administrative details

EU PAS number

EUPAS50473

Study ID

50474

DARWIN EU® study

No

Study countries

United States

Study description

The CIBINQO™ Pregnancy Registry is a US-based, non-interventional, primary data collection cohort study designed to evaluate the association between CIBINQO exposure during pregnancy and subsequent maternal, fetal, and infant outcomes. This registry will enroll pregnant patients of any age who are exposed to CIBINQO during pregnancy and/or have a diagnosis of moderate-to-severe atopic dermatitis. The outcomes of interest are major congenital malformations, minor congenital malformations, spontaneous abortions, stillbirth, elective termination, small for gestational age, preterm birth, postnatal growth deficiency, and infant developmental delay.

Study status

Planned

Research institutions and networks

Institutions

Pfizer

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Institution

Networks

PPD

Contact details

Study institution contact

Jenny Sun Jenny.Sun@pfizer.com

Study contact

Jenny.Sun@pfizer.com

Primary lead investigator

Jenny Sun

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 12/04/2022

Actual: 12/04/2022

Study start date

Planned: 31/01/2023

Date of final study report

Planned: 31/12/2028

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Pfizer

Study protocol

B7451095_ABROCITINIB PROTOCOL_17JUN2022.pdf (663.84 KB)

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:

Assessment of risk minimisation measure implementation or effectiveness

Main study objective:

The CIBINQO™ Pregnancy Registry will add to the current body of knowledge regarding the safety of CIBINQO exposure during pregnancy. This prospective, registry-based, observational cohort study will be conducted to provide information on maternal, fetal, and infant outcomes following exposure to CIBINQO during pregnancy in the post-approval setting.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medical condition to be studied

Dermatitis atopic

Population studied

Age groups

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

Special population of interest

Pregnant women

Estimated number of subjects

400

Study design details

Outcomes

To estimate the crude proportion of maternal, fetal, and infant outcomes of women with moderate-to-severe atopic dermatitis who are exposed to CIBINQO during pregnancy and women with moderate-to-severe atopic dermatitis who are unexposed to CIBINQO during pregnancy. To compare the proportion of maternal, fetal, and infant outcomes between women with moderate-to-severe atopic dermatitis who are exposed to CIBINQO during pregnancy and women with moderate-to-severe atopic dermatitis who are unexposed to CIBINQO during pregnancy, if sample size permits.

Data analysis plan

Demographic and baseline characteristics will be summarized with descriptive statistics for each cohort. For each continuous variable, the number of observations, median, mean, standard deviation, minimum, and maximum for each cohort will be reported. For each categorical variable, the frequency and percentage in each category by cohort will be reported. For each exposure group, the proportion of participants with the outcomes of interest will be calculated. If sample size permits, the proportion of outcomes will be compared between treatment groups.

Data management

Data sources

Data sources (types)

Other

Data sources (types), other

Prospective patient-based data collection

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