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

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Administrative details

Study description

EU PAS number	
EUPAS50473	
Study ID	
50474	
DARWIN FILE Study	
DARWIN EU® study	
No	
Study countries	
United States	

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

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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: 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

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

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

Other	(types)				
Data sources	(types), othe	r			
Prospective pa	ient-based dat	a collectio	n		
Use of a (Common	Data N	Model (CDM)	
CDM mapping					
No					
Data qua	ity spacit	fication	2.5		
Data qua	ity specii	icatioi	15		
Check confor		icatioi	15		
•		icatioi	15		
Check confor	nance	icatioi	15		
Check confor	nance	icatioi	15		
Check conford Unknown Check comple	nance teness	icatioi	15		

Data characterisation

Data characterisation conducted

No