A Post-Marketing Safety Study to Evaluate the Safety of VELSIPITY® (Etrasimod) Exposure During Pregnancy (C5041043)

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Study Planned

Administrative details

EU PAS number

EUPAS1000000672

Study ID

1000000672

DARWIN EU® study

No

Study countries

- [ ] Canada
- [ ] United States

Study description

This study will address the gap in information on the safety of etrasimod when used in pregnancy in terms of risk of maternal, fetal, and infant outcomes.
This non-interventional study is designated as a post-authorization safety study (PASS) and is a post marketing requirement of the FDA.
The research question is: Is there an increased risk of adverse maternal, fetal, or infant outcomes among individuals who are exposed to etrasimod during pregnancy?
The primary objective of the study is to estimate the prevalence of major congenital malformations (MCMs) among pregnant individuals with moderate-to-severe ulcerative colitis (UC) who are exposed to etrasimod during pregnancy.
The secondary objectives of the study are:
• To estimate the prevalence of other maternal, fetal, and infant outcomes among pregnant individuals with moderate-to-severe UC who are exposed to etrasimod during pregnancy.
• To contextualize the prevalence of outcomes among pregnant individuals who are exposed to etrasimod during pregnancy and to estimate the prevalence of all outcomes of interest among pregnant individuals with moderate-to-severe UC who are not exposed to etrasimod during pregnancy.
• If sample size permits, to estimate the risk ratio (RR) for each study outcome comparing the outcomes of pregnant individuals with moderate-to-severe UC who are exposed to etrasimod with those who are not exposed to etrasimod.

Study status

Planned

Research institutions and networks

Institutions

Pfizer

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Institution

CorEvitas

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Shahar Shmuel

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 16/10/2023

Study start date

Planned: 30/09/2025

Date of final study report
Planned: 30/09/2033

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Pfizer 100%

Study protocol

C5041043_ETRASIMOD REVISED PROTOCOL V3.0_01AUG25_clean.pdf (985.85 KB)

Regulatory

Was the study required by a regulatory body?
Yes

Is the study required by a Risk Management Plan (RMP)?
Not applicable

Other study registration identification numbers and links

C5041043

Methodological aspects

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 observational cohort study aims to estimate the prevalence of maternal, fetal, and infant outcomes among individuals with moderate-to-severe UC who are exposed to etrasimod during pregnancy.

Main study objective:

The primary objective of the study is to estimate the prevalence of major congenital malformations (MCMs) among individuals with moderate-to-severe UC who are exposed to etrasimod during pregnancy.

The secondary objectives of the study are:

• To estimate the prevalence of other maternal, fetal, and infant outcomes among pregnant individuals with moderate-to-severe UC who are exposed to etrasimod during pregnancy.

• To contextualize the prevalence of outcomes among pregnant individuals who are exposed to etrasimod during pregnancy, estimate the prevalence of all outcomes of interest among pregnant individuals with moderate-to-severe UC who are not exposed to etrasimod during pregnancy.

• If sample size permits, to estimate risk ratio (RR) for each study outcome

comparing the outcomes of pregnant individuals with moderate-to-severe UC who are exposed to etrasimod with those who are not exposed to etrasimod.

Study drug and medical condition

Medicinal product name

VELSIPITY

Medicinal product name, other

Etrasimod

Study drug International non-proprietary name (INN) or common name

ETRASIMOD

Anatomical Therapeutic Chemical (ATC) code

(L04AE05) etrasimod

etrasimod

Population studied

Short description of the study population

The study population will include two cohorts of pregnant individuals: one cohort of individuals with a diagnosis of moderate-to-severe UC who are exposed to etrasimod at any time during pregnancy and one cohort of individuals with a diagnosis of moderate-to-severe UC who are not exposed to etrasimod during pregnancy.

To be eligible to participate, a patient must be: A resident of the US or Canada, currently pregnant, 15 to 50 years of age at enrollment, and have a diagnosis of

an inflammatory bowel disease.

Special population of interest

Pregnant women

Study design details

Setting

The study will use secondary data collected for the CorEvitas Inflammatory Bowel Disease Pregnancy Registry (IBD-PR), a prospective pregnancy registry based in the US and Canada.

The IBD-PR enrolls pregnant individuals diagnosed with inflammatory bowel diseases, including UC, Crohn’s disease, other and unspecified non-infective gastroenteritis and colitis, or indeterminate colitis.

For this study, participants who are enrolled in the IBD-PR and exposed to etrasimod during pregnancy are eligible for inclusion in the enrolled population, regardless of their IBD diagnosis or severity; however, the analysis population will be limited to those participants who have a diagnosis of moderate-to-severe UC.

Comparators

A cohort of individuals with a diagnosis of moderate-to-severe UC who are not exposed to etrasimod during pregnancy.

Outcomes

The primary outcome of interest is Major congenital malformations (MCMs). The maternal and pregnancy secondary outcomes include minor congenital malformations, pre-eclampsia, eclampsia, spontaneous abortions (SABs), stillbirths, pregnancy terminations, preterm births, small for gestational age,

gestational diabetes, pregnancy-induced hypertension, and placental abruption. The infant secondary outcomes during the first year of life include postnatal growth deficiency, infant developmental delay, infant hospitalization, infant infections (both serious and non-serious), and infant death.

Data analysis plan

Participant characteristics will be summarized with descriptive statistics for each cohort. Comparative analyses will be conducted for each outcome if sample size permits.

Supplementary analyses will be conducted that include pregnant individuals who were excluded from the analysis population.

If sample size permits, subgroup and sensitivity analyses will be performed to examine the extent to which changes in certain methods or assumptions affect the results.

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 Inflammatory Bowel Disease Pregnancy Registry (IBD-PR)

Data sources (types)

Disease registry

Pregnancy 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