Observational Cohort Study of Safety of Etrasimod During Pregnancy in US Claims Databases (C5041042)

First published: 19/06/2026

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Study Planned

Administrative details

EU PAS number

EUPAS1000000832

Study ID

1000000832

DARWIN EU® study

No

Study countries

United States

Study description

This non-interventional study (NIS) is designated as a post-authorization safety study (PASS) and is a commitment to the US FDA. This is an observational cohort study using two US-based administrative healthcare claims databases, each of which will be used to identify pregnancy episodes among individuals with UC who are exposed to etrasimod during pregnancy or who are unexposed to etrasimod but exposed to other advanced UC treatments during pregnancy.

Research question: Is there an increased risk of adverse pregnancy and/or infant outcomes in individuals who are exposed to etrasimod during pregnancy?

Primary objective: Describe the prevalence of major congenital malformations (MCMs) in infants born alive to pregnant individuals with a diagnosis of ulcerative colitis (UC) who are (1) exposed to etrasimod during pregnancy (Etrasimod Cohort) and (2) unexposed to etrasimod but exposed to other advanced UC treatments during pregnancy (Other Advanced UC Treatments Cohort) and compare the prevalence between cohorts if sample size permits

Secondary objective: Describe the prevalence of pregnancy (spontaneous abortion, pregnancy termination, gestational hypertension, pre-eclampsia, eclampsia, and stillbirth) and infant (preterm birth and small for gestational age) outcomes among individuals in the Etrasimod Cohort and the Other Advanced UC Treatments Cohort and compare the prevalence between cohorts if sample size permits

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Study status

Planned

Research institutions and networks

Institutions

Pfizer

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Institution

Optum; Carelon

Contact details

Study institution contact

Julia Beasley julia.munroe@pfizer.com

Study contact

julia.munroe@pfizer.com

Primary lead investigator

Shahar Shmuel

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 20/12/2023

Actual: 20/12/2023

Study start date
Planned: 17/11/2026

Data analysis start date
Planned: 01/06/2031

Date of interim report, if expected
Planned: 30/11/2027

Date of final study report
Planned: 31/03/2032

Sources of funding

- Pharmaceutical company and other private sector

Study protocol

C5041042ETRASIMODREVISEDPROTOCOLV3023MAR20261.pdf (721.43 KB)

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

C5041042

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 an observational cohort study that will be conducted within two US-based health insurance claims databases.

Main study objective:

Primary objective: Describe the prevalence of major congenital malformations (MCMs) in infants born alive to pregnant individuals with a diagnosis of UC who are (1) exposed to etrasimod during pregnancy (Etrasimod Cohort) and (2) unexposed to etrasimod but exposed to other advanced UC treatments during pregnancy (Other Advanced UC Treatments Cohort) and compare the prevalence between cohorts if sample size permits

Secondary objective: Describe the prevalence of pregnancy (spontaneous abortion, pregnancy termination, gestational hypertension, pre-eclampsia, eclampsia, and stillbirth) and infant (preterm birth and small for gestational age) outcomes among individuals in the Etrasimod Cohort and the Other Advanced UC Treatments Cohort and compare the prevalence between cohorts if sample size permits

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name

VELSIPITY

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 consist of pregnant individuals with UC and an estimated date of conception between 5 January 2023 and 30 September 2028 (with outcomes observed through 30 September 2029) who were exposed to etrasimod or other advanced UC treatments during pregnancy.

Special population of interest

Pregnant women

Study design details

Setting

All qualifying pregnancies during the study period within two US-based health insurance claims databases among individuals with UC who are exposed to etrasimod during pregnancy or individuals with UC who are not exposed to etrasimod but who are exposed to other advanced UC treatments during pregnancy will be included.

Comparators

Cohort of individuals with UC who are unexposed to etrasimod but are exposed to other advanced UC treatments during pregnancy.

Outcomes

The primary outcome of this study is major congenital malformation (MCM).

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. One interim report will describe accrual of eligible patients into each of the study cohorts. The interim report will also describe each cohort according to key outcome characteristics and outcome counts. The final report will provide the same cohort descriptions, as well as the prevalence of each study outcome by cohort. If sample size permits, the final report will also include a comparative analysis utilizing inverse probability of treatment weighting that estimates the relative prevalence of each of the study outcomes, with the primary analysis of MCMs restricted to cases confirmed by medical record review. All analyses will be conducted and reported separately by data source, and a meta-analysis combining results across databases will also be performed.

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

Optum Research Database (ORD)

Healthcare Integrated Research Database (HIRD)

Data sources (types)

Administrative healthcare records (e.g., claims)

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