

# Prospective, Registry-Based Observational Cohort Study of Zavegepant Safety in Pregnancy

**First published:** 18/10/2024

**Last updated:** 12/06/2025

Study

Planned

## Administrative details

### EU PAS number

EUPAS1000000335

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### Study ID

1000000335

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### DARWIN EU® study

No

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### Study countries

 United States

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### Study description

In March 2023, the US FDA approved zavegepant (ZAVZPRET) for the acute treatment of migraine with or without aura in adults. Zavegepant is the first CGRP receptor antagonist available to patients in nasal spray form. CGRP receptor antagonists represent the newest class of migraine treatments that reduce pain through interfering with CGRP-induced vasodilation and inflammation.

Migraine is common, especially among women, with a prevalence of 21% in US women and 10% in US men. Prevalence peaks in mid-life and women of reproductive age carry the greatest migraine burden. Migraine is associated with a higher risk of some adverse pregnancy outcomes including pre-eclampsia and gestational hypertension.

While no adverse developmental effects were observed in zavegepant animal studies, there are limited data on the safety of zavegepant use in pregnant individuals (ZAVZPRET label 2023). This study will address this gap in information on the safety of zavegepant when used in pregnancy in terms of risk of maternal and/or infant outcomes. This will be a new, product-based registry that recruits pregnant women with migraine as well as pregnant women taking zavegepant. This non-interventional study (NIS) is designated as a postauthorization safety study (PASS) and is a post-marketing commitment to the FDA.

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### **Study status**

Planned

## Research institutions and networks

### Institutions

## Pfizer

**First published:** 01/02/2024

**Last updated:** 01/02/2024

Institution

## Pharmaceutical Product Development (PPD)

**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

Monica Bertoia

Primary lead investigator

## Study timelines

**Date when funding contract was signed**

Planned: 17/06/2024

Actual: 17/06/2024

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**Study start date**

Planned: 31/10/2024

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**Data analysis start date**

Planned: 01/01/2025

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**Date of interim report, if expected**

Planned: 30/06/2025

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**Date of final study report**

Planned: 30/06/2038

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Pfizer 100%

## Study protocol

[C5301026\\_ZAVEGEPANT PREGNANCY REGISTRY](#)

[PROTOCOL\\_V3.0\\_06SEP2024.pdf](#) (982.13 KB)

## Regulatory

**Was the study required by a regulatory body?**

Yes

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

Not applicable

**Other study registration identification numbers and links**

C5301026

**Methodological aspects**

**Study type**

**Study type list**

**Study topic:**

Human medicinal product

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**Study type:**

Non-interventional study

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**Scope of the study:**

Safety study (incl. comparative)

**Data collection methods:**

Primary data collection

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**Study design:**

A registry-based, prospective observational cohort study

**Main study objective:**

1. To estimate the prevalence of MCM births (primary outcome) among pregnant individuals with migraine who are (1) exposed to zavegepant (internal exposed cohort), and (2) unexposed to zavegepant (internal comparator cohort).
2. To estimate the RR of MCM births in the exposed internal cohort versus the unexposed internal cohort.

## Study Design

**Non-interventional study design**

Cohort

## Study drug and medical condition

**Medicinal product name, other**

Zavzpret

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

MIGLUSTAT

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**Anatomical Therapeutic Chemical (ATC) code**

(A16AX06) miglustat

## Population studied

### **Short description of the study population**

Pregnant individuals 15 to 50 years of age in the US, including individuals with migraine exposed to zavegepant during pregnancy and individuals with migraine unexposed to zavegepant during pregnancy.

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### **Age groups**

- Adults (18 to < 65 years)
    - Adults (18 to < 46 years)
    - Adults (46 to < 65 years)
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### **Special population of interest**

Pregnant women

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### **Estimated number of subjects**

728

## Study design details

### **Setting**

The 2 internal study cohorts will be derived from eligible individuals enrolled in the pregnancy registry. The virtual registry coordinating center (VRCC) will coordinate enrollment and data collection for the internal study cohorts (details provided in Protocol Section 9.4). The external nonmigraine cohort will include individuals identified within the claims database. All 3 cohorts of pregnant

individuals will be identified in the US during the study period.

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## **Comparators**

Internal comparator cohort

All remaining eligible individuals who are not exposed to zavegepant during pregnancy will be included in the comparator cohort. This cohort will include individuals who are and are not exposed to migraine treatments.

External nonmigraine cohort

An external cohort of pregnant individuals without migraine will provide context to the main study results by estimating background rates of the study outcomes among pregnant individuals. This cohort will be identified within the ORD, a US-based health insurance claims database. See Protocol Section 9.4.5 for details about the ORD. Methods for identifying and characterizing the external nonmigraine cohort are described in detail in Annex 1, the draft protocol “Observational Cohort Study of Zavegepant Safety in Pregnancy Within a US Claims Database.”

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## **Outcomes**

MCM is the primary outcome of interest and all other outcomes are secondary. All outcome data are collected via HCPs. Protocol Table 1 presents the definitions of the outcomes of interest.

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## **Data analysis plan**

Detailed methodology for summary and statistical analyses of data collected in this study will be documented in a statistical analysis plan (SAP), which will be dated, filed and maintained by the Sponsor. The SAP may modify the plans outlined in the protocol; any major modifications of primary endpoint definitions or their analyses would be reflected in a protocol amendment.

## **Documents**

## Study report

[c5301026-interim1-report-body.pdf](#) (779.8 KB)

## 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

Primary data collection

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### Data sources (types)

[Pregnancy registry](#)

## Use of a Common Data Model (CDM)

### CDM mapping

No

## Data quality specifications

**Check conformance**

Unknown

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**Check completeness**

Unknown

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**Check stability**

Unknown

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**Check logical consistency**

Unknown

## Data characterisation

**Data characterisation conducted**

Unknown