## Adakveo (crizanlizumab) PRegnancy outcomes Intensive Monitoring (PRIM) (Adakveo (crizanlizumab) PRIM)

First published: 18/02/2021

**Last updated:** 08/05/2024





### Administrative details

**Study description** 

EU PAS number	
EUPAS39412	
Study ID	
47770	
DARWIN EU® study	
No	
Study countries	
Switzerland	

This is a non-interventional study to evaluate pre-specified pregnancy and infant outcomes in women treated with crizanlizumab during pregnancy or within 105 days before the last menstrual period (LMP). It is based on pharmacovigilance data from the Novartis global safety database on pregnancy cases that are eligible for the study. Although pharmacovigilance data may be collected from any country in the world where the product is approved, the anonymized patient level data will be analyzed at a global level in Switzerland.

#### **Study status**

Ongoing

### Research institutions and networks

### **Institutions**

### **Novartis Pharmaceuticals**

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Institution

### Contact details

### Study institution contact

Novartis Clinical Disclosure Officer trialandresults.registries@novartis.com

Study contact

#### **Primary lead investigator**

### Novartis Clinical Disclosure Officer

**Primary lead investigator** 

### Study timelines

#### Date when funding contract was signed

Planned: 10/07/2020 Actual: 10/07/2020

#### Study start date

Planned: 15/11/2020 Actual: 15/11/2020

#### **Date of final study report**

Planned: 15/05/2031

### Sources of funding

• Pharmaceutical company and other private sector

### More details on funding

**Novartis** 

### Study protocol

Protocol\_SEG101 PRIM\_10July2020\_clean\_Redacted.pdf (364.16 KB)

### Regulatory

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

No

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

Non-EU RMP only

# Other study registration identification numbers and links

CSEG101A2404

### Methodological aspects

### Study type

### Study type list

### Study type:

Non-interventional study

### Scope of the study:

Safety study (incl. comparative)

### Main study objective:

The primary objective is to estimate the proportion of pregnancies resulting in fetal loss (intrauterine death resulting in stillbirth, spontaneous abortion, or induced termination), among pregnant women exposed to crizanlizumab within 105 days prior to LMP or at any time during pregnancy

### Study Design

#### Non-interventional study design

Cohort

Other

#### Non-interventional study design, other

Intensive monitoring schemes

### Study drug and medical condition

#### Name of medicine

**ADAKVEO** 

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

**CRIZANLIZUMAB** 

#### **Anatomical Therapeutic Chemical (ATC) code**

(B06AX01) crizanlizumab

crizanlizumab

#### Medical condition to be studied

Sickle cell disease

### Population studied

#### Age groups

Adolescents (12 to < 18 years)

Adults (18 to < 46 years)

Adults (46 to < 65 years)

#### Special population of interest

Pregnant women

#### **Estimated number of subjects**

500

### Study design details

#### **Outcomes**

Fetal loss (intrauterine death resulting in stillbirth, spontaneous abortion, or induced termination), Congenital malformations

#### Data analysis plan

Data analysis will focus on the prospectively reported pregnancy cases. Descriptive analysis will be performed for prospective pregnancy cases including case disposition and maternal characteristics by providing the number and percentage of pregnancies in each category. Distributions of continuous variables will be summarized with means, standard deviations, medians, and range. Categorical variables will be summarized with proportions. Numbers and proportions (with 95% confidence intervals) for pregnancy outcomes will be reported. Adverse outcomes will be examined by trimester of exposure and concomitant exposure to hydroxyurea/hydroxycarbamide. Case details will be provided separately for retrospective cases.

### 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 sources (types)**

Other

Spontaneous reports of suspected adverse drug reactions

#### Data sources (types), other

Novartis Global Safety database

### Use of a Common Data Model (CDM)

### **CDM** mapping

No

### Data quality specifications

#### **Check conformance**

Unknown

### **Check completeness**

Unknown

### **Check stability**

### **Check logical consistency**

Unknown

### Data characterisation

### **Data characterisation conducted**

No