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

First published: 18/02/2021

Last updated: 08/05/2024

Study Ongoing

Administrative details

PURI

https://redirect.ema.europa.eu/resource/47770

EU PAS number

EUPAS39412

Study ID

47770

DARWIN EU® study

No

Study countries

☐ Switzerland

Study description

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

Study contact

trialandresults.registries@novartis.com

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

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

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No