Adakveo (crizanlizumab) PRegnancy outcomes Intensive Monitoring (PRIM)

First published: 18/02/2021

Last updated: 26/03/2026

Study Finalised

Administrative details

EU PAS number

EUPAS39412

Study ID

47770

DARWIN EU® study

No

Study countries

Switzerland

Study description

This was 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 was based on

pharmacovigilance data from the Novartis global safety database on pregnancy cases that were eligible for the study. Although pharmacovigilance data may had been collected from any country in the world where the product was approved, the anonymized patient level data was analyzed at a global level in Switzerland.
Although the study initiated in 2020, the marketing authorizations for Adakveo® were revoked or suspended in several countries, including the EU in Aug-2023, following the study results of CSEG101A2301. As of 30-Jun-2025, there were fewer than 15 pregnancies in the crizanlizumab PRIM study. Given the very low number of patients in the study and the low probability of substantial increase in the sample size, the crizanlizumab PRIM study was terminated prematurely

Study status

Finalised

Research institutions and networks

Institutions

Novartis Pharmaceuticals

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Last updated: 01/02/2024

Institution

Contact details

Study institution contact

Novartis Clinical Disclosure Officer

trialandresults.registries@novartis.com

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

Data analysis start date

Actual: 30/06/2025

Date of final study report

Planned: 14/11/2031

Actual: 30/10/2025

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 topic:

Disease /health condition

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:

The crizanlizumab PRIM study is a non-interventional study (NIS) based on secondary use of data from a set of targeted follow-up (TFU) checklists with structured follow-up on pregnancies reported to the Novartis global safety database. This study is single-arm, descriptive in nature

Main study objective:

The primary objective was 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

Medicinal product name

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

Short description of the study population

All prospective and retrospective pregnancy cases exposed to crizanlizumab during pregnancy or 105 days before LMP reported to the Novartis global safety database were eligible for the PRIM program.

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.

Documents

Abstract of study report

CSEG101A2404 Report Component Report Body Abstract_Redacted.pdf (67.76 KB)

Study report

CSEG101A2404 Report Component- Report Body (1).pdf (339.64 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

Novartis global safety database

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