Outcomes of romiplostim for chemotherapy-induced thrombocytopenia (CIT) in solid tumors (20220113)

First published: 05/04/2024

Last updated: 27/11/2026

Study Ongoing

Administrative details

EU PAS number

EUPAS1000000067

Study ID

1000000067

DARWIN EU® study

No

Study countries

United States

Study status

Ongoing

Research institutions and networks

Institutions

Amgen

United States

First published: 01/02/2024

Last updated: 27/03/2026

Institution

Contact details

Study institution contact

Global Development Leader Amgen Inc.

medinfo@amgen.com

Study contact

medinfo@amgen.com

Primary lead investigator

Global Development Leader Amgen Inc.

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 22/11/2024

Actual: 12/11/2024

Study start date
Planned: 25/11/2024

Actual: 12/11/2024

Data analysis start date
Planned: 16/12/2024

Date of final study report
Planned: 31/07/2025

Sources of funding

- Pharmaceutical company and other private sector

Study protocol

Redacted Protocol-Published Original romiplostim 20220113 .pdf (3.2 MB)

Regulatory

Was the study required by a regulatory body?

No

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

Non-EU RMP only

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Data collection methods:

Secondary use of data

Main study objective:

To summarize proportion of participants achieving full platelet response following initiation of romiplostim for CIT.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name

NPLATE

Medicinal product name, other

Nplate®, romiplostim

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

ROMIPLOSTIM

Anatomical Therapeutic Chemical (ATC) code

(B02BX04) romiplostim

romiplostim

Additional medical condition(s)

Solid tumors

Population studied

Age groups

- Adults (18 to < 46 years)
- Adults (46 to < 65 years)
- Adults (65 to < 75 years)
- Adults (75 to < 85 years)

Study design details

Outcomes

Primary Outcomes:

• Platelet count ≥ 100 x 10^9/L and at least 30 x 10^9/L higher than pretreatment baseline.

Secondary Outcomes:

• Thrombocytopenia-related antineoplastic therapy dose modification (dose delay, dose reduction, dose discontinuation, or dose omission).

• Time to platelet count ≥ 100 x 10^9/L and at least 30 x 10^9/L higher than pretreatment baseline after romiplostim initiation.
• Platelet treatment events (transfusion or administration of non-romiplostim thrombopoietin receptor agonist (TPO-RA)).
• Clinical events of interest (bleeding events, thromboembolic events, all-cause hospitalizations, hospitalizations for bleeding and thromboembolic events, and development of myelodysplastic syndromes or secondary malignancies).
• Platelet count ≥ 100 x 109/L
• Inequality symbols are broken

Data analysis plan

All primary and secondary analyses are descriptive in nature. Summary statistics will be used to describe and characterize the cohort. Means (standard deviations) and medians (interquartile ranges) will be summarized for continuous variables, and frequencies and proportions will be shown for categorical variables. The primary objective is a proportion which will be reported as a percentage, with a 95% confidence interval. The secondary objectives are a mix of proportions, incidence rates, and time to event analyses. Proportion will be reported in the same manner as above for the primary objective. Incidence rates will be reported as events per 100 person-years with 95% confidence interval. Time to event analyses will be reported as Kaplan-Meier median with 95% confidence interval.

Data management

Data sources

Data source(s), other

Research Patient Data Registry (RPDR)

Data sources (types)

Electronic healthcare records (EHR)

Other

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

No

Check completeness

Yes

Check stability

No

Check logical consistency

No

Data characterisation

Data characterisation conducted

No