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

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Study | Planned

Administrative details

PURI
https://redirect.ema.europa.eu/resource/1000000067

EU PAS number
EUPAS1000000067

Study ID
1000000067

DARWIN EU® study
No

Study countries
United States

Study status
Planned

Research institution and networks

Institutions

Amgen

United States
First published: 01/02/2024
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Institution

Contact details

Study institution contact
Global Development Leader Amgen Inc.

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:
10/05/2024

Study start date
Planned:
15/09/2024

Data analysis start date
Planned:
19/02/2025

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

Sources of funding

- Pharmaceutical company and other private sector

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 data collection

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

Name of medicine
Nplate

Name of medicine, other
Nplate®, romiplostim

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

Anatomical Therapeutic Chemical (ATC) code
(B02BX04) 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).

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