A post-authorisation, non-interventional, retrospective, drug-utilisation study to describe the pattern of use of lenalidomide in patients with myelodysplastic syndromes (MDS) (CC-5013-MDS-012)

First published: 12/03/2018

Last updated: 05/02/2025

Study | Finalised

Administrative details

EU PAS number

EUPAS22604

Study ID

47927

DARWIN EU® study

No

Study countries

- ☐ Austria
- ☐ Czechia

- [ ] Denmark
- [ ] France
- [ ] Germany
- [ ] Greece
- [ ] Netherlands
- [ ] Poland
- [ ] Portugal
- [ ] Spain
- [ ] Sweden
- [ ] United Kingdom (Northern Ireland)
- [ ] United States

Study description

This is a post-authorisation, non-interventional, retrospective, drug-utilisation study. This study will be run in countries in the EU in which Revlimid (lenalidomide) is approved and marketed for the MDS indication and where these patients were subsequently granted access to the drug through reimbursement schemes.

The only exception is that eligible patients from the company-sponsored Connect® Myeloid Disease Registry (US Cohort Registry) will be included regardless of start date of treatment to assess the secondary safety objectives (but not the primary drug-utilisation objective due to a different MDS indication approved in the US).

This retrospective drug-utilisation study will include patients with MDS treated with lenalidomide, irrespective if within or outside the authorized indication in the EU (eg, patients commencing lenalidomide treatment for transfusion-dependent IPSS low- or int-1-risk MDS with isolated del(5q) or with additional cytogenetic abnormalities, or IPSS risk categories intermediate-2 (int-2) -or high, or patients with MDS without del(5q) will also be recorded).

Study status

Finalised

Research institutions and networks

Institutions

Celgene International

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Institution

Contact details

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Primary lead investigator

BRISTOL MYERS SQUIBB COMPANY Celgene International Sarl

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 30/11/2017

Actual: 31/07/2018

Study start date
Planned: 31/10/2018

Actual: 08/11/2018

Date of interim report, if expected
Planned: 31/03/2019

Actual: 21/03/2019

Date of final study report
Planned: 28/06/2024

Actual: 21/05/2024

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

CELGENE INTERNATIONAL SARL, a BRISTOL MYERS SQUIBB COMPANY

Study protocol

Protocol Amendment 3 (Version 2.0) 12 Apr 2023_Redacted.pdf (866.2 KB)

Regulatory

Was the study required by a regulatory body?

Yes

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

EU RMP category 1 (imposed as condition of marketing authorisation)

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Main study objective:

To describe the pattern of use of lenalidomide in clinical routine practice of MDS in EU countries in which Revlimid® (lenalidomide) is marketed for the treatment of patients with transfusion-dependent anaemia due to low- or intermediate-1-risk myelodysplastic syndromes associated with an isolated deletion 5q cytogenetic abnormality when other therapeutic options are insufficient or inadequate.

Study drug and medical condition

Medicinal product name

REVLIMID

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

LENALIDOMIDE

Anatomical Therapeutic Chemical (ATC) code

(L04AX04) lenalidomide

lenalidomide

Medical condition to be studied

Myelodysplastic syndrome

Population studied

Short description of the study population

Those MDS patients who have received at least one dose of lenalidomide and who started their treatment after lenalidomide has obtained EU Regulatory approval for the MDS indication and in countries that subsequently had a positive reimbursement decision with the exception of eligible patients from the company-sponsored Connect® Myeloid Disease Registry (US Cohort Registry) who will be included regardless of start date of treatment.

Age groups

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

- Adults (85 years and over)

Estimated number of subjects

460

Study design details

Outcomes

To describe the pattern of use of lenalidomide in the clinical routine practice of MDS patients in the countries concerned.
To further describe the safety of lenalidomide both within the EU approved indication on-label cohort and outside of the EU approved indication (i.e., in patients with any type of MDS other than transfusion-dependent International Prognostic Scoring System IPSS low- or intermediate-1 int-1-risk MDS with isolated del(5q)) off-label cohort.

Data analysis plan

MDS patients who are outside of the labeled EU indication will be further characterized as to the following: · IPSS Status (Int-2 or High).
· Presence of additional cytogenetic abnormalities (yes/no) and characterization of type of additional cytogenetic abnormalities based upon the Revised International Prognostic Scoring System (IPSS-R) classification.
· Lack of documentation of transfusion-dependent status or documentation of transfusion burden insufficient to meet accepted criteria for transfusion-dependence.

Documents

Study report

CC-5013-MDS-012_FSR Abstract_Redacted.pdf (2.68 MB)

Data management

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)

Danish registries (access/analysis)

Data source(s), other

- EUMDS - Myelodysplastic Syndrome
- Spanish Registry of MDS or RE SMD (Registro Español de Síndromes Mielodisplásicos)
- Düsseldorf MDS Registry
- online French Registry of MDS
- Danish National Acute Leukemia Registry

Data sources (types)

Disease registry

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