A Non-interventional, Post-authorization Safety Study of Patients with Relapsed or Refractory Mantle Cell Lymphoma to Further Investigate and Characterize the Association of Lenalidomide With Tumor Flare Reaction and High Tumor Burden (CC-5013-MCL-005)

First published: 02/05/2018

Last updated: 19/01/2026

Study Finalised

Administrative details

EU PAS number

EUPAS23366

Study ID

47194

DARWIN EU® study

No

Study countries

Austria

France

Germany

Greece

Italy

Netherlands

Spain

Study description

The purpose of this study is to investigate and characterize the association of lenalidomide with tumor flare reaction and high tumor burden in patients with relapsed or refractory mantle cell lymphoma.

Study status

Finalised

Research institutions and networks

Institutions

Celgene International

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Worldwide Patients Safety Celgene International Sarl

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 26/10/2017

Study start date

Planned: 28/02/2019

Actual: 20/07/2018

Data analysis start date

Planned: 31/12/2026

Actual: 10/01/2024

Date of final study report

Planned: 31/12/2027

Actual: 24/10/2024

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Celgene

Study protocol

cc-5013-mcl-005-protamend5-0_redacted.pdf (4.28 MB)

Regulatory

Was the study required by a regulatory body?

Yes

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

EU RMP category 3 (required)

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Main study objective:

To quantify and characterize tumor flare reaction (TFR) by tumor burden (assessed based on last CT scan performed within up to 2 months prior to initiation of lenalidomide administration) in Relapsed Refractory Mantle Cell Lymphoma (R/R MCL) patients treated with lenalidomide in a real-world setting

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Retrospective non-interventional study

Study drug and medical condition

Medicinal product name, other

lenalidomide

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

LENALIDOMIDE

Anatomical Therapeutic Chemical (ATC) code

(L04AX04) lenalidomide

lenalidomide

Medical condition to be studied

Mantle cell lymphoma

Population studied

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

105

Study design details

Outcomes

To quantify and characterize the event of tumor flare reaction (TFR) in R/R MCL patients treated with lenalidomide. To quantify and characterize the proportion of early deaths (defined as deaths within 20 weeks of the initial administration of lenalidomide) by tumor burden in R/R MCL patients treated with lenalidomide.

Data analysis plan

The analysis will be descriptive and no a priori hypotheses will be tested. All analyses will be stratified according to baseline tumor burden. The proportion of patients with high tumor burden at baseline will be estimated with its two-sided 95% CI. The cumulative incidence of TFR and early death will be calculated. The frequency of TFR and other adverse events related to lenalidomide collected and not listed in the current SmPC will also be reported in summary tables. Any TFR events will be descriptively reported for up to 6 months of treatment. Time to event analyses and incidence rates for TFR and early death will be estimated using the Kaplan-Meier method. Since data is being collected retrospectively, the number of time points each patient may have will be unknown a priori. KM analyses will not be performed as primary but as complementary analyses. Exploration of factors associated with TFR and with early death will be conducted in multivariate analyses.

Documents

Study report

cc-5013-mcl-005-csr-final-study-report_redacted_Redacted.pdf (12.94 MB)

Study, other information

CC-5013-MCL-005_Site List_10Jun2020.pdf (70.45 KB)

CC-5013-MCL-005_Site List_2022-05-16.pdf (96.49 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 sources (types)

Other

Data sources (types), other

Retrospective patient-based data collection

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