# 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:** 07/03/2024

Study Ongoing

## 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**

Ongoing

# Research institutions and networks

## Institutions

### Celgene International

**First published:** 01/02/2024

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**Institution**

# Contact details

**Study institution 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

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**Study start date**

Planned: 28/02/2019

Actual: 20/07/2018

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**Data analysis start date**

Planned: 31/12/2026

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**Date of final study report**

Planned: 31/12/2027

## 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

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

EU RMP category 3 (required)

# Methodological aspects

## Study type

## Study type list

**Study type:**

Non-interventional study

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**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

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**Non-interventional study design, other**

Retrospective non-interventional study

## Study drug and medical condition

**Anatomical Therapeutic Chemical (ATC) code**

(L04AX04) lenalidomide

lenalidomide

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**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)

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**Estimated number of subjects**

560

## 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.

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**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, 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

## 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