

# Clinical Characteristics of The First IMLYGIC™ Patients With Unresectable Stage IIIB-IVM1a Melanoma Treated in Routine Clinical Practice, in Selected European Countries (20140413)

**First published:** 26/01/2017

**Last updated:** 22/02/2024

Study

Finalised

## Administrative details

### EU PAS number

EUPAS17410

---

### Study ID

32544


---

### DARWIN EU® study


No


---

### Study countries

 Austria

 Germany

 Netherlands

 United Kingdom

---

## Study description

The treatment landscape for melanoma (including targeted and immunotherapies) continues to evolve rapidly. There is a lack of available data outside of the clinical trial setting in relation to the patient, disease and treatment characteristics of patients who are prescribed IMLYGICTM as melanoma therapy, and the respective physician's prescribing behaviour and rationale. Real-world data is thus warranted to inform on usual care practice with regards to IMLYGICTM use for the treatment of adults with unresectable metastatic melanoma. The purpose of this study is to collect data on the first EU patients receiving IMLYGICTM in a real world setting.

---


## Study status

Finalised

# Research institutions and networks

## Institutions

Amgen

 United States

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

**Last updated:** 27/03/2026

Institution

Multiple centres: 9 centres are involved in the study

## Contact details

### Study institution contact

Global Development Leader Amgen Inc.  
medinfo@amgen.com

Study contact

[medinfo@amgen.com](mailto:medinfo@amgen.com)

### Primary lead investigator

Global Development Leader Amgen Inc.

Primary lead investigator

## Study timelines

### Date when funding contract was signed

Planned: 28/03/2016

Actual: 28/03/2016

---

### Study start date

Planned: 31/07/2017

Actual: 29/06/2017

---

**Data analysis start date**

Planned: 01/05/2019

Actual: 14/04/2019

---

**Date of final study report**

Planned: 18/11/2019

Actual: 25/10/2019

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Amgen

## Study protocol

[01.02.05 Special Protocol Ver 1.0 2016-10-28 English.pdf](#) (451.13 KB)

[20140413 01.02.06 Public Redacted Protocol Ver 1.0 English.pdf](#) (227.41 KB)

## Regulatory

**Was the study required by a regulatory body?**

No

---

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

Not applicable

## Methodological aspects

### Study type

**Study topic:**

Human medicinal product

Disease /health condition

---

**Study type:**

Non-interventional study

---

**Scope of the study:**

Disease epidemiology

Drug utilisation

**Data collection methods:**

Secondary use of data

---

**Main study objective:**

To characterise patients with melanoma at time of first IMLYGIC™ administration in terms of demographics, disease history, and clinical and tumour characteristics

## Study Design

**Non-interventional study design**

Other

---

**Non-interventional study design, other**

Retrospective observational chart review study

## Study drug and medical condition

**Medicinal product name**

IMLYGIC

---

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

TALIMOGENE LAHERPAREPVEC

---

**Anatomical Therapeutic Chemical (ATC) code**

(L01XX51) talimogene laherparepvec

talimogene laherparepvec

---

**Medical condition to be studied**

Malignant melanoma stage III

Malignant melanoma stage IV

## Population studied

**Short description of the study population**

Unresectable stage IIIB-IVM1a melanoma patients who received at least an initial IMLYGIC® dose at a concentration of 10<sup>6</sup> plaque forming units (PFU)/mL and at least one subsequent dose at a concentration of 10<sup>8</sup> PFU/MI as per the EU marketing authorisation during the study eligibility period, was 18 years of age or older at the time of first IMLYGIC® administration, and patient/legal representative provided informed consent, where required.

---

**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)
- 

### **Special population of interest**

Other

---

### **Special population of interest, other**

Melanoma patients

---

### **Estimated number of subjects**

60

## Study design details

### **Outcomes**

Characterise patients with melanoma at time of first IMLYGIC™ administration in terms of demographics disease history and clinical and tumour characteristics, • Use of IMLYGIC • Use of other melanoma treatment • Clinical outcomes and events of interest • Describe physician's decision making process and rationale for prescribing

---

### **Data analysis plan**

Analysis will be descriptive with appropriate statistical methods (ie, mean, standard deviation, median, quartiles, minimum and maximum for continuous variables, numbers and percentages for categorical variables).

## Documents

### **Study results**

## 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)

[Electronic healthcare records \(EHR\)](#)

## 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