# A Postmarketing Prospective Cohort Study of Melanoma Patients Treated With IMLYGIC® (Talimogene Laherparepvec) in Clinical Practice to Characterize the Risk of Herpetic Infection Among Patients, Close Contacts, and Health Care Providers (20130193)

**First published:** 07/10/2016

**Last updated:** 01/07/2024

Study    Ongoing

## Administrative details

**EU PAS number**

EUPAS15128

**Study ID**

20631

**DARWIN EU® study**

No

**Study countries**

☐ Austria

☐ Finland

☐ Norway

☐ Sweden

☐ United States

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**Study description**

Cohort study of melanoma patients for up to 5 years after the first IMLYGIC dose.

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**Study status**

Ongoing

# Research institutions and networks

## Institutions

### Amgen

☐ United States

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

**Last updated:** 21/02/2024

**Institution**

Multiple centres: 35 involved in the study

# Contact details

**Study institution contact**

Global Development Leader Amgen Inc.

medinfo@amgen.com

( 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: 01/05/2016

Actual: 01/05/2016

**Study start date**

Planned: 14/08/2017

Actual: 10/08/2017

**Data analysis start date**

Planned: 06/08/2038

**Date of final study report**

Planned: 06/08/2038

# Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Amgen Inc.

## Study protocol

[Protocol-Published Original talimogene laherparepvec 20130193 .pdf](#) (5.89 MB)

[Protocol-Published Superseding talimogene laherparepvec 20130193 5 .pdf](#)
(4.86 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

**Study design:**

This postmarketing prospective cohort study will follow melanoma patients for up to 5 years after the first IMLYGIC dose in clinical practice. There is no experimental intervention, and the study population will receive standard-of-care treatment as determined by their treating physician.

**Main study objective:**

The primary objective is to estimate the incidence rate of herpetic infection with detection of talimogene laherparepvec DNA among patients for up to 5 years after the first IMLYGIC dose.

# Study Design

**Non-interventional study design**

Cohort

# Study drug and medical condition

**Medicinal product name**

IMLYGIC

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

TALIMOGENE LAHERPAREPVEC

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**Anatomical Therapeutic Chemical (ATC) code**

(L01XX51) talimogene laherparepvec

talimogene laherparepvec

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**Medical condition to be studied**

Malignant melanoma

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**Additional medical condition(s)**

Herpetic Infection

# 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**

300

# Study design details

**Outcomes**

Incidence of herpetic infection with detection of talimogene laherparepvec DNA among patients, - Count of herpetic infections with detection of talimogene laherparepvec DNA among close contacts and HCPs- Summary of patient

characteristics- Treatment patterns of anticancer therapy (eg, types and sequence)- Incidence of use of anti-herpetic therapy- Incidence of adverse events and serious adverse events during treatment with IMLYGIC- Overall survival

**Data analysis plan**

The statistical analysis will be entirely descriptive and no formal hypothesis will be tested.

# 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**

Exposure 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