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

PURI

https://redirect.ema.europa.eu/resource/20631

EU PAS number

EUPAS15128

Study ID

20631

DARWIN EU® study

No

Study countries

- ☐ Austria
- ☐ Finland
- ☐ Norway
- ☐ Sweden
- ☐ United States

Study description

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

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.

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

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

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

Name of medicine

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

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)

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

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