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 availabledata 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

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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

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 106 plaque forming units (PFU)/mL and at least one subsequent dose at a concentration of 108 PFU/Ml 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

20140413 Observational Research Study Report Abstract.pdf (194.6 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)

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