Characterization of the metastatic melanoma population in Chile that received ipilimumab for the treatment of unresectable or metastatic melanoma

First published: 10/03/2014

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Study Finalised

Administrative details

EU PAS number

EUPAS6036

Study ID

32322

DARWIN EU® study

No

Study countries

☐ Chile

Study description

THIS STUDY WAS CANCELED ON DECEMBER 17, 2013 DUE TO LACK OF PI PARTICIPATION.The study will retrospectively collect data from clinical records at all the sites where adult unresectable or MM adult patients treated with at least one dose of ipilimumab therapy in Chile

Study status

Finalised

Research institutions and networks

Institutions

Bristol-Myers Squibb (BMS)

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Institution

Multiple centres: 15 centres are involved in the study

Contact details

Study institution contact

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Study contact

Christian.Yanez@bms.com

Primary lead investigator

Christian Yanez

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 01/04/2013

Study start date

Actual: 01/07/2013

Date of final study report

Planned: 30/04/2014

Actual: 17/12/2013

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Bristol-Myers Squibb

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 type list

Study topic:

Human medicinal product

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Other

If ‘other’, further details on the scope of the study

Basal features of melanoma patients treated with ipilimumab

Data collection methods:

Secondary use of data

Main study objective:

The primary objective of the study is to characterize the metastatic melanoma (MM) population, inChile, that received ipilimumab for the treatment of unresectable or MM.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Non-randomised clinical trial, Retrospective medical records review

Study drug and medical condition

Name of medicine

YERVOY

Medical condition to be studied

Acral lentiginous melanoma stage IV

Population studied

Short description of the study population

Metastatic melanoma patients who received ipilimumab for MM, in Chile from January 2011 through January 2013.

Age groups

Adults (18 to < 46 years)

Adults (75 to < 85 years)

Adults (85 years and over)

Special population of interest

Other

Special population of interest, other

Metastatic melanoma patients

Estimated number of subjects

0

Study design details

Outcomes

Descriptions of study variables requested by the MoH are provided below:AgeGenderEAP/PrivateDiagnosisStagePerformance StatusPrevious Treatment LinesFirst Infusion dateIpilimumab doseNumber of infusionsRe-inductionFollow-upAdverse EventDate of death

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Data analysis plan

All study variables will be analyzed descriptively.This study was not required by any local Health Authority (not mandatory).

Data management

Data sources

Data sources (types)

Other

Data sources (types), other

Retrospective medical records

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