

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

**First published:** 10/03/2014

**Last updated:** 14/11/2019

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

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### Study status

Finalised

## Research institutions and networks

### Institutions

**Bristol-Myers Squibb (BMS)**

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

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**Institution**

**Multiple centres:** 15 centres are involved in the study

## Contact details

### Study institution contact

Christian Yanez [Christian.Yanez@bms.com](mailto:Christian.Yanez@bms.com)

### Study contact

[Christian.Yanez@bms.com](mailto:Christian.Yanez@bms.com)

### Primary lead investigator

Christian Yanez

### Primary lead investigator

## Study timelines

### Date when funding contract was signed

Actual: 01/04/2013

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### Study start date

Actual: 01/07/2013

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### 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

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**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

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**Study type:**

Non-interventional study

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**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

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**Main study objective:**

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

## Study Design

### **Non-interventional study design**

Other

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### **Non-interventional study design, other**

Non-randomised clinical trial, Retrospective medical records review

## Study drug and medical condition

### **Medicinal product name**

YERVOY

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### **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.

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### **Age groups**

- Adults (18 to < 46 years)
- Adults (75 to < 85 years)
- Adults (85 years and over)

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### Special population of interest

Other

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### Special population of interest, other

Metastatic melanoma patients

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### Estimated number of subjects

0

## Study design details

### Outcomes

Descriptions of study variables requested by the MoH are provided below: Age Gender EAP/Private Diagnosis Stage Performance Status Previous Treatment Lines First Infusion date Ipilimumab dose Number of infusions Re-induction Follow-up Adverse Event Date 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

## 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

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### Data sources (types), other

Retrospective medical records

## Use of a Common Data Model (CDM)

### CDM mapping

No

## Data quality specifications

### Check conformance

Unknown

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### Check completeness

Unknown

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### Check stability

Unknown

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## **Check logical consistency**

Unknown

## Data characterisation

### **Data characterisation conducted**

No