Ipilimumab 12-month intensive pharmacovigilance protocol

First published: 10/03/2014

Last updated: 01/04/2024

Study Finalised

Administrative details

EU PAS number

EUPAS6033

Study ID

28053

DARWIN EU® study

No

Study countries

Venezuela, Bolivarian Republic of

Study description

This protocol is being conducted to comply with the direct request from the HA for a 12-month intensive pharmacovigilance protocol of all patients in Venezuela treated with ipilimumab for advanced (unresectable, recurrent or

metastatic melanoma). The primary objective of the protocol is to identify and describe observed adverse events (AEs) while on treatmentwith ipilimumab for advanced melanoma in Venezuela during the protocol period of 12 months.

Study status

Finalised

Research institutions and networks

Institutions

Bristol-Myers Squibb (BMS)

First published: 01/02/2024

Last updated: 01/02/2024

Institution

JSS Medical Research Inc, Multiple centres: 30 centres are involved in the study

Contact details

Study institution contact

osvaldo colatruglio Osvaldo.Colatruglio@bms.com

Study contact

Osvaldo.Colatruglio@bms.com

Primary lead investigator

osvaldo colatruglio

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 10/12/2013

Actual: 10/12/2013

Study start date

Actual: 10/02/2014

Data analysis start date

Actual: 15/05/2015

Date of interim report, if expected

Actual: 10/09/2015

Date of final study report

Planned: 02/04/2015

Actual: 28/01/2016

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Bristol-Myers Squibb Company

Regulatory

Was the study required by a regulatory body?

Yes

Is the study required by a Risk Management Plan (RMP)?

EU RMP category 1 (imposed as condition of marketing authorisation)

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Data collection methods:

Primary data collection

Main study objective:

The primary objective of the protocol is to identify and describe observed adverse events (AEs) while on treatmentwith ipilimumab for advanced melanoma in Venezuela during the protocol period.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Intensive pharmacovigilance

Study drug and medical condition

Medicinal product name

YERVOY

Medical condition to be studied

Acral lentiginous melanoma stage IV

Population studied

Short description of the study population

All patients in Venezuela treated with ipilimumab for advanced (unresectable, recurrent or metastatic melanoma).

Age groups

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

Estimated number of subjects

35

Study design details

Outcomes

AEs reported while on ipilimumab will be recorded during the protocolduration.

Data analysis plan

The protocol is designed as a descriptive analysis. All variables will be analyzed descriptively, and presented as monthly line listing reports and a final report as per the request of the Venezuelan HA.

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

Prospective patient-based data collection

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

Unknown