Ipilimumab 12-month intensive pharmacovigilance protocol

First published: 10/03/2014

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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)

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Institution

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

Contact details

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Study contact

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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

Name of medicine

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

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