A Multi-National, Prospective, Observational Study in Patients with Unresectable or Metastatic Melanoma (IMAGE)

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Last updated: 09/02/2021

Study Finalised

Administrative details

EU PAS number

EUPAS2723

Study ID

39442

DARWIN EU® study

No

Study countries

- [ ] Australia
- [ ] Austria
- [ ] Brazil
- [ ] Canada

- [ ] France
- [ ] Germany
- [ ] Greece
- [ ] Hungary
- [ ] Ireland
- [ ] Norway
- [ ] Poland
- [ ] Spain
- [ ] Sweden
- [ ] Switzerland
- [ ] United Kingdom

Study description

The IMAGE study is a multi-national, prospective, observational study with a minimum of 3 years follow-up to understand how ipilimumab is being used in previously-treated patients diagnosed with unresectable or metastatic melanoma, its safety profile, and the manner in which adverse reactions are managed in routine clinical practice worldwide. Further, this study will provide information on the influence that the availability of ipilimumab as a treatment option exerts on the following health outcomes for patients with unresectable or metastatic melanoma: real-world patterns of care, humanistic outcomes of treatment, such as quality of life and work productivity, healthcare resource utilization, treatment effectiveness (overall survival).

Study status

Finalised

Research institutions and networks

Institutions

Bristol-Myers Squibb (BMS)

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Institution

Multiple centres: 200 centres are involved in the study

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Julie Scotto

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 30/08/2011

Study start date
Planned: 30/04/2012

Actual: 26/04/2012

Date of final study report
Planned: 28/12/2018

Actual: 06/11/2018

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 3 (required)

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Drug utilisation

Effectiveness study (incl. comparative)

Safety study (incl. comparative)

Data collection methods:

Primary data collection

Main study objective:

1) To estimate the incidence and severity of adverse reactions in adult patients treated withipilimumab in the post-approval setting2) To describe the management of adverse reactions and their outcomes inipilimumab-treated patients in the post-approval setting

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Name of medicine

YERVOY

Medical condition to be studied

Metastatic malignant melanoma

Population studied

Short description of the study population

Patients diagnosed with unresectable or metastatic melanoma.

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

Metastatic malignant melanoma patients

Estimated number of subjects

1800

Study design details

Outcomes

- Incidence rate with person-year-exposure, frequency estimate of AE/SAE- Frequency at which immunosuppressive therapy was administered to manage treatment-related ARs associated with ipilimumab- Descriptive statistics to assess patterns of care: treatment, dosing, regimen, indication, treatment rationales, management of treatment-related AE, reasons for treatment discontinuation, - Resource utilization associated with advanced melanoma treatment: descriptive statistics will be reported for healthcare utilization (inpatient, outpatient, emergency department and other ancillary services) and imputed costs

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Data analysis plan

Descriptive data will be provided for treatment-related ARs that occur in the study population, frequency data for these ARs will be reported in aggregate. The incidence rate of all ARs among patients receiving ipilimumab will be determined (N/100 patient years) and a 95% CI will be provided. Incidence will be reported both cumulatively and by year since initiation of treatment. In addition, descriptive statistics will be provided for data regarding the management and outcome of ARs associated with use of ipilimumab. Descriptive statistics and multivariate logistic regression will be used to analyze patterns of care. Descriptivestatistics will also be reported to evaluate healthcare utilization and costs, and analysis of covariance will also be used for patient reported outcomes regarding quality of life. Overall survival and PFS probabilities will be estimated using Kaplan-Meier (KM) method, with medians and corresponding two-sided 95% confidence intervals.

Data management

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

No