Pattern of Use and Safety/Effectiveness of Nivolumab in Routine Oncology Practice (CA209234)

First published: 10/10/2016

Last updated: 08/02/2021

Study Ongoing

Administrative details

EU PAS number

EUPAS14071

Study ID

39427

DARWIN EU® study

No

Study countries

- ☐ Australia
- ☐ Austria
- ☐ Belgium
- ☐ Czechia

- [ ] France
- [ ] Germany
- [ ] Hungary
- [ ] Italy
- [ ] Poland
- [ ] Spain
- [ ] Switzerland
- [ ] United Kingdom
- [ ] United States

Study description

This is an observational, single-arm, multicenter, prospective cohort study in patients treated with nivolumab for the approved indications of melanoma and lung cancer in Australia, the EU, Switzerland, and the United States (US). Targeted countries in the EU for study participation include Austria, Belgium, France, Germany, Italy, Spain, and the United Kingdom (UK). Study objectives are to assess the safety experience, survival, adverse event management, and outcomes of adverse events associated with nivolumab in routine oncology care facilities. The study population includes 400 adults treated with nivolumab for histologically or cytologically confirmed melanoma and 800 adults treated with nivolumab for histologically or cytologically confirmed lung cancer. The study will be started in 2016, and data collection will be continued until March 2024.

Study status

Ongoing

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Scotto Julie

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 17/07/2015

Actual: 17/07/2015

Study start date

Planned: 31/07/2016

Actual: 29/07/2016

Data analysis start date

Planned: 30/08/2016

Actual: 29/07/2016

Date of interim report, if expected

Planned: 11/09/2018

Actual: 10/09/2018

Date of final study report

Planned: 31/12/2024

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)?

EU RMP category 3 (required)

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Main study objective:

As additional pharmacovigilance measure in the post-approval EU RMP for nivolumab, the study will assess the use pattern and safety/effectiveness profile

of nivolumab and the management strategies and outcomes of identified risks associated with nivolumab treatment for melanoma and lung cancer in routine oncology practice. This study will generate data to inform future risk minimization efforts.

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Observational, multicenter, single-arm study

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(L01XC17) nivolumab

nivolumab

Medical condition to be studied

Metastatic malignant melanoma

Non-small cell lung cancer metastatic

Population studied

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

Immunocompromised

Estimated number of subjects

1200

Study design details

Outcomes

Primary Endpoints:Immune-related pneumonitisImmune-related colitisImmune-related hepatitisImmune-related nephritis/renal dysfunctionImmune-related endocrinopathies Immune-related skin reactions Other immune-related, adverse reactionsSevere infusion reactions, Secondary Endpoints:Other nivolumab treatment-related AEsManagement of Immune-related AEsOutcomes of Immune-related AEsOverall SurvivalNivolumab treatment pattern

Data analysis plan

Incidence rates of immune-related AEs as in primary objective calculated separately for melanoma and lung cancer. Other immune-related AEs analyzed as combined endpoint. # and % of patients whose immune-related AEs are managed according to recommended strategies will be summarized. Approaches to diagnose AEs are summarized by # and % for immune-related AEs. Doses/duration of systemic corticosteroids, of non-corticosteroid treatment, hormone therapies/other treatment modalities will be summarized.

AE Outcomes to present with # and % of patients experiencing outcomes presented separately for those managed with recommended algorithms and those not. Data on deaths to summarize as follows: # and % of all deaths, of deaths ≤ 30d of last dose received, of deaths ≤ 1 to 5 yrs after initiation of nivolumab. Analyze survival with Kaplan-Meier plots. Calculate survival rates & the corresponding 95% CIs, median survival and 95% CIs.

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

No