Retrospective Chart Review Study of First-Line Treatment Patterns and Clinical Outcomes in Patients with Advanced (Unresectable or Metastatic) Melanoma in the United Kingdom (1L Melanoma Chart Review Study in UK)

First published: 07/09/2017

Last updated: 14/03/2024

Study | Planned

Administrative details

EU PAS number

EUPAS20861

Study ID

22040

DARWIN EU® study

No

Study countries

United Kingdom

Study description

Main study objective is to describe the first-line best overall response (BOR) rate in a subset of treatment-naïve patients who received first-line regimen (nivolumab + ipilimumab). Secondary objectives are to describe first-line systemic therapy treatment patterns for advanced (unresectable or metastatic) melanoma and systemic therapy sequencing patterns including the proportion of patients who are tested for PD-L1 status including threshold used for first-line treatment selection. In a subset of patients who received first-line regimen (nivolumab + ipilimumab), additional outcome measures are: treatment-free interval (TFI), progression-free survival (PFS), the proportion of patients remaining on treatment following disease progression, 12 months overall survival (OS), adverse events of special interest (AESI) (includes select gastrointestinal, renal, pulmonary, hepatic, endocrine, skin, neurological, and infusion reactions) and serious adverse events (SAEs) (CTCAE grades 3+ AEs) including AESI management (prophylaxis and treatment), and healthcare resource utilisation (HRU). Exploratory objectives include describing factors associated with first-line treatment selection and predictors of first-line treatment response in a subset of patients treated with regimen.

Study status

Planned

Research institutions and networks

Institutions

Addenbrooke's Hospital

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Corrie Pippa

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 23/06/2017

Study start date

Planned: 19/12/2017

Data analysis start date

Planned: 03/04/2018

Date of final study report

Planned: 01/05/2018

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Bristol-Myers Squibb Research and Development

Regulatory

Was the study required by a regulatory body?

No

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

Not applicable

Other study registration identification numbers and links

CA209-9TW

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Effectiveness study (incl. comparative)

Safety study (incl. comparative)

Other

If ‘other’, further details on the scope of the study

Safety management

Main study objective:

To determine the first-line best overall response (BOR) rate in a subset of treatment-naïve patients who received first-line nivolumab+ipilimumab combination therapy

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Additional medical condition(s)

Advanced (unresectable or metastatic) melanoma

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)

Estimated number of subjects

400

Study design details

Outcomes

Best overall tumour response (complete response (CR), partial response (PR), stable disease, progressive disease, not evaluable, unknown) will be assessed. Best overall response rate (BOR) will be defined as total number of patients whose BOR between treatment initiation and earliest of initiation of next line of therapy or chart abstraction date = CR or PR, divided by total number of patients. Patient demographics, disease characteristics, prior melanoma treatment history, first-line systemic therapy treatment patterns, treatment sequencing, clinical outcomes (treatment-free interval, progression-free survival, 12 month overall survival), proportion of patients tested for PD-L1 status, safety, safety management, healthcare resource utilisation

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Data analysis plan

Data analysis will be primarily descriptive. For continuous variables, mean, standard deviation, median, minimum, and maximum will be provided, and for categorical variables, numbers and percentages for each category will be provided. Analysis will be stratified by sub-groups (e.g. biomarker status,

treatment type) where data availability permits. treatment-free interval, progression-free survival, and 12 month overall survival will be analysed using the Kaplan-Meier method. Chi-squared tests may be used to identify potential patient characteristics associated with first-line therapy selection and predictors of response, for patients on regimen. Additionally, binary or multinomial logistic regression or Mantel-Haenszel procedure and Cox proportional hazards model may be used.

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

Retrospective data collection from patient medical charts. Data extracted directly from site EMRs where possible and/or abstracted from patient medical records for entry into an electronic data capture (EDC) system.

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