Prospective International Observational Cohort Study Assessing Safety Outcomes Among Squamous Non-small Cell Lung Cancer Patients Treated with Necitumumab in Combination with Gemcitabine and Cisplatin in Comparison to Patients Treated with Cisplatin-based Doublets (I4X-MC-B002)

First published: 18/10/2018

Last updated: 17/05/2024

Study Finalised

Administrative details

EU PAS number

EUPAS12595

Study ID

29241

DARWIN EU® study

No

Study countries

☐ Austria

☐ Germany

Study description

To evaluate the safety of necitumumab administered in combination withgemcitabine and cisplatin in comparison to cisplatin doublets for treatment of adult patients with locally advanced or metastatic squamous non-small cell lung cancer who have not received prior chemotherapy for this condition

On 15-Feb-2021, the EU license for Portrazza (Necitumumab) expired in EU, and a decision was made by
the Sponsor to terminate the non-interventional PASS B002 study.

Study status

Finalised

Research institutions and networks

Institutions

IQVIA

☐ United Kingdom

First published: 12/11/2021

Last updated: 22/04/2024

Institution | Non-Pharmaceutical company | ENCePP partner

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Ana Sofia Afonso

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 12/10/2016

Study start date

Planned: 28/02/2019

Actual: 11/03/2019

Date of final study report

Planned: 29/12/2023

Actual: 15/02/2021

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Eli Lilly and Company

Study protocol

B002 PASS Protocol (1)_Redacted.pdf(513.19 KB)

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 type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Main study objective:

To characterise and compare the incidence of select adverse events inlocally advanced or metastatic squamous non-small cell lung cancer patients receiving treatment of necitumumab in combination with gemcitabine and cisplatin or patients treated with cisplatin-based doublets under real-world conditions

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Study drug International non-proprietary name (INN) or common name

NECITUMUMAB

Medical condition to be studied

Non-small cell lung cancer

Population studied

Short description of the study population

Cohort 1 ~667 patients receiving first-line necitumumab in combination with gemcitabine and cisplatin treatment, Cohort 2 ~333 patients receiving first-line cisplatin-based doublets without necitumumab

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

1000

Study design details

Outcomes

The safety outcomes of interest include thromboembolic events, cardiorespiratory disorders, and severe electrolyte disturbances, Real-world use of thromboprophylaxis, real-world management of hypomagnesaemia, incidence of other treatment-emergent adverse events of interest under real-world conditions, ECGs as obtained in target population, EGFR protein expression status as well as EGFR and KRAS mutation status, supportive care and hospitalization(s) and reasons for hospitalization(s) of target population

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Data analysis plan

Descriptive analyses (including standard univariate analyses) will be conducted to evaluate demographic and clinical characteristics and crude incidence proportion and rate of AEs. Categorical measures will be summarised as counts and percentages, while continuous measures will be summarised using mean, median, standard deviation, and range.Propensity score stratification will be performed to adjust for baseline differences in potential confounding factors to compare the risk of AEs of interest in patients receiving first-line necitumumab in combination with gemcitabine and cisplatin to those who receive other first-

line cisplatin-based doublets.

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