

# 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

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### Study ID

29241


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**DARWIN EU® study**

No

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### Study countries

 Austria

 Germany

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### Study description

To evaluate the safety of necitumumab administered in combination with gemcitabine 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.

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### 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

[afonso\\_anasofia@lilly.com](mailto:afonso_anasofia@lilly.com)

### Primary lead investigator

Ana Sofia Afonso

Primary lead investigator

## Study timelines

### Date when funding contract was signed

Actual: 12/10/2016

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### Study start date

Planned: 28/02/2019

Actual: 11/03/2019

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### 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

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### **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

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##### **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 in locally 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

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### **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

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### **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)
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### **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

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

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### 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

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### Check completeness

Unknown

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### Check stability

Unknown

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**Check logical consistency**

Unknown

**Data characterisation**

**Data characterisation conducted**

No