Survival follow up of JO25567, a randomized phase 2 study comparing erlotinib and bevacizumab combination with erlotinib alone in NSCLC patients harboring EGFR mutation.

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Study Finalised

Administrative details

EU PAS number

EUPAS25131

Study ID

25132

DARWIN EU® study

No

Study countries

Japan

Study description

A follow up study to JO25567 comparing overall survival in NSCLC patients harboring EGFR mutation between two treatment groups - bevacizumab plus erlotinib versus erlotinib alone.

Study status

Finalised

Research institutions and networks

Institutions

Novartis Pharmaceuticals

Contact details

Study institution contact

Minoru Watanabe global.clinical_trial_registry@roche.com

Study contact

global.clinical_trial_registry@roche.com

Primary lead investigator

Minoru Watanabe

Primary lead investigator

Study timelines

Date when funding contract was signed
Actual: 23/04/2014

Study start date
Actual: 13/06/2014

Date of final study report
Actual: 19/06/2018

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Chugai Pharmaceutical Co., Ltd.

Study protocol

Protocol (v1.2).pdf (1.04 MB)

Regulatory

Was the study required by a regulatory body?

Yes

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

EU RMP category 1 (imposed as condition of marketing authorisation)

Other study registration identification numbers and links

JO29424

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Data collection methods:

Primary data collection

Main study objective:

The study followed patients with EGFR mutated NSCLC who completed Study JO25567 with the aim to compare the overall survival of the patients who received bevacizumab plus erlotinib to those who were treated with Erlotinib alone.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

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

BEVACIZUMAB

Medical condition to be studied

Non-small cell lung cancer

Population studied

Short description of the study population

Patients with EGFR mutated NSCLC who completed Study JO25567: a Randomized Phase 2 Study Comparing Erlotinib and Bevacizumab Combination with Erlotinib Alone in NSCLC Patients Harboring EGFR Mutation.

Age groups

- Adults (18 to < 46 years)
- Adults (46 to < 65 years)
- Adults (65 to < 75 years)

Special population of interest

Other

Special population of interest, other

Non-small cell lung cancer patients

Estimated number of subjects

75

Study design details

Outcomes

The primary efficacy endpoint in this study was Overall Survival, defined as the time from the date of randomization in the JO25567 study to the date of death irrespective of the cause.

Data analysis plan

Overall Survival curves for each treatment group are estimated using the Kaplan-Meier product limit method. Median values of OS and survival rate, along with two-sided 95% CI, are calculated. A log-rank test was also applied to compare the distribution between groups. Associated 95% confidence interval are calculated using the Greenwood formula. Furthermore, the Cox regression analysis was applied and the hazard ratios and their 95% confidence intervals estimated. Kaplan-Meier curve were displayed and created raw output of LIFETEST procedure.

Documents

Study results

Synopsis.pdf (246.14 KB)

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